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FDA PUBLIC MEETING 10/27/2016

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FOOD AND DRUG ADMINISTRATION (FDA)

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WORKSHOP

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ON

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REFURBISHING, RECONDITIONING, REBUILDING, REMARKETING,

7

REMANUFACTURING, AND SERVICES OF MEDICAL DEVICES

8

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Thursday, October 27, 2016

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FDA White Oak Campus

14

10903 New Hampshire Avenue

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Silver Spring, Maryland 20993

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Reported by: Nate Riveness

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3 William Maisel, FDA

4 Bryan Benesch, FDA

5 Robert Sauer, FDA

6 Diane Mitchell, FDA

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1 P R O C E E D I N G S

2 OPENING REMARKS

3 MS. FLOURNOY: So, I am Valerie Flournoy.
4 I'm the Deputy Director for the Division of
5 Manufacturing Quality in the Office of Compliance
6 CDRH. I thank you all for coming here today. And so
7 I am going to give you some housekeeping information
8 for you.

9 So, you know about ordering the box lunch
10 and as we told you that we had to get orders and we
11 will be talking with the Sodexo (ph) after this to
12 determine like when lunch how it is easiest for you
13 all that have not paid, how we can facilitate it much
14 more easier than the long lines. But any time if you
15 need any type of assistance there are supposed to have
16 tags and it is really pink, not red, if you would just
17 raise your hand or ask one of us anything, we'll be
18 able to assist you with your questions if we can or
19 direct you to the proper person. If you aren't
20 already the restrooms are if you go out the door and
21 go to your right and all the way to the wall past the
22 dexo and to the right down the hall there's a men's

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1 and ladies restrooms are, except where some of the
2 overflow rooms are where there is only one bathroom
3 stall.

4 Some of these sessions allow for questions
5 and answers. So the people that are on the webcast we
6 do have an email mailbox and you see it
7 thirdpartyserviceworkshop@FDA.hhs.gov can forward your
8 questions and our moderator will read the questions
9 off to our panel. Those of you that are sitting in
10 the overflow rooms, we have index cards and we will
11 bring the index cards to you and we will pick them up
12 and bring the questions in here for our moderators to
13 read.

14 So just enjoy. Right now I'd like to
15 introduce Dr. William Maisel. He's the Deputy
16 Director for Science and Chief Scientist for the
17 Center of Devices and Radiological Health that will
18 provide the Welcome.

19 WELCOME

20 DR. MAISEL: Thanks Valerie. And good
21 morning. On behalf of FDA and CDRH welcome to our
22 workshop and we very much appreciate you being here.

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1 It is a pretty amazing time to be involved in the
2 medical device industry. We have devices that can
3 help blind patients to see, paraplegic patients to
4 walk, we have heart valves that can be implanted
5 through a thin catheter without open heart surgery.
6 Just last month we approved the world's first
7 artificial pancreas that can control both low and high
8 blood glucose levels; pretty amazing innovation.

9 We've seen innovation and creativity in
10 digital health. Many of you have a smart phone in
11 your pocket. Some of you may have some of your health
12 information on there. We have patients who can
13 control their medical devices literally from their
14 pocket.

15 We've seen incredible innovation in device
16 design and materials and manufacturing; the burgeoning
17 of 3-D printing. And it is not just technology that
18 has evolved. It is healthcare delivery that has
19 evolved. And many of you are health organizations and
20 patients are facing cost pressures, a lot of attention
21 on cost effectiveness and value.

22 And so in this environment it seems very

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1 timely to talk about refurbishing, reconditioning,
2 rebuilding, remarketing, remanufacturing and servicing
3 of medical devices. And as an aside it might be our
4 longest workshop title ever.

5 [Laughter]

6 And clearly these functions serve a critical
7 role. And we recognize the importance of these
8 activities not only to the health of the healthcare
9 ecosystem but also to the health of our patients.

10 At the outset I'd also really like to
11 acknowledge that we are aware of many organizations
12 and many professionals who perform these activities
13 very well whether it be an independent service
14 organization, an original equipment manufacturer, a
15 healthcare facility, biomedical or clinical engineers,
16 healthcare technology management professionals or
17 other entities.

18 But we've also heard from various
19 stakeholders who have sometimes expressed concerns
20 about the quality, safety and continued effectiveness
21 of medical devices that have been subject to one or
22 more of these activities. And we're really here to

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1 get your perspective on these things.

2 We've heard about some stakeholders, for
3 example, have expressed concerns about the use of
4 unqualified personnel to perform service, maintenance,
5 refurbishment and device alterations on equipment and
6 that the work performed may not adequately be
7 documented. We've heard from others that have noted
8 the difficulty in gaining access to device
9 specifications, access to service equipment and
10 replacement parts needed to assure that the work being
11 performed returns the device to the proper state.

12 And these are not just theoretical concerns.
13 We've seen real world examples of improperly serviced
14 and refurbished medical devices such as those
15 involving radiological products and endoscopes that
16 can result in disabled device safety features,
17 improper unexpected device operation and most
18 importantly that could have a negative impact on the
19 safety of our patients or on the operators of these
20 devices.

21 We've also heard about some of the best
22 practices. We've heard about some organizations and

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1 individuals that use these best practices to overcome
2 and address some of these challenges that I just
3 mentioned such as having a quality management system,
4 training that assures that individuals performing
5 these activities have adequate knowledge, skill and
6 experience, and a focus on providing high quality
7 service that restores or maintains devices to their
8 original or intended specifications.

9 What is clear is that FDA can't and
10 shouldn't tackle these challenges alone. We want to
11 hear from you. We want you to share your thoughts,
12 your perspectives, your insights, your experiences and
13 your ideas and that is why we are here over the next
14 two days.

15 The design of this workshop includes
16 presentations from stakeholders, panel discussions on
17 key issues and an opportunity for you to share your
18 viewpoints on each of these topics. And we'll be
19 discussing what's currently being done to assure
20 patient safety and what gaps, if any, need to be
21 addressed.

22 Ultimately it is our hope to identify common

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1 ground and consensus around some of the best practices
2 for these activities.

3 I should note that while I mentioned
4 endoscopes the reprocessing of reusable medical
5 devices is not within the scope of this workshop. The
6 Agency has taken a number of actions and steps to
7 strengthen the reprocessing of reusable medical
8 devices and we won't be discussing that topic further
9 here today.

10 And ultimately there is one common purpose
11 that unites each of us in this room and that is our
12 desire to focus on the health and well-being of our
13 patients and on the individuals that use these
14 products. We are here to listen to you so that
15 together we can map out what, if anything, should be
16 done; what additional actions or steps as a community
17 we should think about taking. And importantly this is
18 really the beginning of the dialogue; not the end.
19 And so there will be additional opportunities beyond
20 this workshop for public input on any actions or
21 things that the Agency thinks should be the next steps
22 following this workshop.

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1 So again thank you for being here. We look
2 forward to a productive two days. And now it is my
3 distinct pleasure and honor to introduce our next
4 speaker who is Bryan Benesch. Bryan is the Deputy
5 Director for Regulatory Oversight and Analysis in our
6 Division of Analysis and Program Operations in our
7 Office of Compliance; and he's really a walking
8 history book about FDA and these activities. And so
9 you should be looking forward and I am looking forward
10 to hearing from Bryan about our history of regulation
11 in this area.

12 HISTORY OF FDA INVOLVEMENT WITH REFURBISHING,
13 RECONDITIONING, REBUILDING, REMARKETING,
14 REMANUFACTURING, AND SERVICING OF MEDICAL DEVICES
15 PERFORMED BY THIRD-PARTY ENTITIES AND ORIGINAL
16 EQUIPMENT MANUFACTURERS

17 MR. BENESCH: Thank you, Dr. Maisel.

18 So in the beginning FDA published its first
19 guidance on refurbishers and reconditioners way back
20 in 1987 in something called a compliance policy guide
21 which is what our field organization would follow and
22 these were public documents so manufacturers and other

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1 regulated entities were aware of it. And back in 1987
2 our policy was that reconditioners and rebuilders were
3 basically subject to all requirements. They had to
4 register every year. At that time registration was
5 free. If they were doing something to a product that
6 required a 510(k) they needed to follow one; they had
7 to comply with the labeling requirements in the 801;
8 they were subject to inspection; they had to comply
9 with GMPs and DR (device reporting). So in the
10 beginning of the process we treated refurbishers and
11 reconditioners no different than a manufacturer.

12 Then the quality system regulation came
13 along. And there was a decision in '93 to update what
14 was then the CGMPs and we wanted to codify basically
15 what the policy was. And so the proposed rule
16 included third-party servicers and refurbishers as
17 being subject to all of the proposed changes in the
18 new quality system regulation.

19 Well, there were a lot of comments about
20 this; there was a lot of contentious discussions about
21 it. And it got to the point where this particular
22 subject could have derailed the proposed rule from

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1 becoming final. So the Agency based on the comments
2 and the advisory committee meeting decided not to
3 include this change in the final rule.

4 So when the final rule for the quality
5 system regulation was published it said FDA believes
6 that persons who perform such functions as a servicer
7 or refurbisher meet the definition of a manufacturer
8 but that we've elected to address this in a separate
9 rulemaking later this year, 1996. And a separate
10 rulemaking would also cover third-party service
11 organizations. So 20 years ago.

12 So 1997 we actually published what is known
13 as Advance Notice of Public Rulemaking which is sort
14 of the pre-step of having a proposed rule. And this
15 is where the refurbisher, reconditioner, servicers,
16 all that verbiage comes from. We had 89 public
17 comments. We didn't do anything subsequent to
18 receiving those comments except the following: So the
19 ANPR said FDA's announcing its intention to review and
20 if necessary to revise or amend the compliance policy
21 guide that was issued in 1987 and the regulatory
22 requirements related to remarketing of used medical

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1 devices and the persons who refurbish, recondition,
2 rebuild, service and remarket such devices. At that
3 time no one could agree what the right term was. And
4 I think we are still at that point where nobody really
5 knows what the best term to use for this particular
6 situation is.

7 We also went on to say we believe evolving
8 industry practices warrant reevaluation of the current
9 policy and the application of certain regulatory
10 requirements in order to ensure that particular
11 remarketed devices meet suitable performance
12 requirements for their intended use and are as safe as
13 the originally marketed finished devices. So 20 years
14 ago we said the same thing that Dr. Maisel basically
15 just re-indicated.

16 We went on to indicate what sections of the
17 law we felt these entities needed to be subject to and
18 it dealt with the same things, you know, recalls,
19 labeling, quality, medical device reporting, the
20 medical device tracking; and then because there are
21 radiologic health products involved the imaging
22 equipment x-rays, et cetera, all of those sections in

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1 the electronic product radiation control portions of
2 the act.

3 After that meeting there was a lot of
4 discussion as to how to proceed and whether or not the
5 Agency should promulgate a regulation or whether or
6 not there should be a voluntary process. So FDA
7 joined with AAMI and there was a public meeting, two
8 days, in September of 1998 to discuss what the best
9 approach would be.

10 Out of that meeting there came a task force
11 which met for about a year that had representatives
12 from all of the affected parties and they drafted a
13 report, a joint medical device industry proposed
14 alternative to the regulation of servicers,
15 refurbishers and remarketers. The proposal suggested
16 that there be voluntary controls that the industry
17 itself would administer and monitor so that FDA would
18 not have an official role. Some of those things that
19 were proposed at the time was a voluntary registration
20 process; I believe a voluntary certification process
21 so that user facilities that were using these parties
22 would understand that they had met a basic level of

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1 understanding as to how to appropriately refurbish and
2 service the products. That report was submitted to
3 FDA I believe in late '99 or maybe the following year.

4 Then we decided we had to do a little
5 housekeeping. So we still had that 1987 compliance
6 policy guide that was still out there saying that we
7 were going to continue to regulate refurbishers and
8 reconditioners. But since we had said in the preamble
9 of the final quality system regulation that we were
10 going to not do that we issued a notice saying that
11 basically we're withdrawing all regulatory oversight
12 of refurbisher and servicers with the exception of the
13 overarching Food, Drug and Cosmetic Act requirements
14 that if there is a public health issue we can still
15 assert our authority.

16 Since 1998 no one has had to register with
17 us, no one has been subject to inspection except for
18 cause if there is a concern that you are not really
19 refurbishing but you are actually remanufacturing a
20 device because you are changing the intended use. So
21 the industry has not really had any involvement with
22 FDA except our interactions with some of the trade

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1 associations since 1998.

2 So here we are today. So in March we
3 published the request for comment about this subject.
4 We got 177 comments, more than twice what we got 20
5 years ago. And we are here today to talk about what
6 those comments said and some of the other issues that
7 were raised.

8 Now I was here 20 years ago. So I'm one of
9 the few people that have been through this process for
10 quite some time. In fact I was here in 1987.

11 Now I have the pleasure of introducing Rob
12 Sauer. Rob is a Policy Analyst in CBH's Office of In
13 Vitro Diagnostics and Radiologic Health. Rob has
14 experience as a reviewer of pre-market submissions and
15 compliance issues for both medical devices and
16 radiation emitting electronic products. Rob will be
17 presenting working definitions for this meeting and an
18 overview of stakeholder input to date. And I believe
19 we were going to post the definitions.

20 Rob?

21 WORKING DEFINITIONS AND OVERVIEW OF STAKEHOLDER
22 PERSPECTIVES

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1 MR. SAUER: Thank you. So I will be
2 presenting working definitions today. And in the
3 agenda everyone received on the second page you should
4 find a copy of those working definitions.

5 So Mr. Benesch just finished reviewing the
6 history of FDA's involvement on this issue. And I now
7 have the opportunity to review some of the more recent
8 history in this space.

9 First I'll go over some working definitions
10 that were developed for the purposes of this workshop
11 and then I'll review some of the other feedback we've
12 received.

13 In March we proposed and requested feedback
14 on definitions for six different terms that relate to
15 the topic of today's workshop. The terms were
16 recondition, service, repair, refurbish, remanufacture
17 and remarket. We requested feedback on these terms
18 because we've encountered people applying them
19 differently and we want to know how people are
20 actually using them. We also wanted to know if there
21 were any activities that we hadn't considered that we
22 should consider and also to establish working

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1 definitions for the purposes of this workshop.

2 On the next few slides I'll list these
3 working definitions; they are changed slightly from
4 the definitions proposed in the FR Notice. And these
5 changes were made based on the comments we received
6 and to improve clarity. We don't think that we had
7 enough information or feedback to provide a final and
8 comprehensive set of definitions and we realize that
9 clarifications may be needed as we go forward with
10 next steps.

11 So just to make sure we are all clear on
12 what these definitions are. They are working
13 definitions for today. They are not new regulatory
14 definitions. And if you are speaking at this workshop
15 and you want to use these terms in a way other than
16 how they are defined that is okay. Please just be
17 clear about that to avoid any confusion. And as I
18 mentioned revisions, clarifications and distinctions
19 may be necessary going forward.

20 So the first definition we have here is
21 remanufacture. And so that is to process, condition,
22 renovate, repackage, restore or any other acts done to

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1 a finished device that significantly changes the
2 finished devices performance or safety specifications
3 or intended use. This is only slightly modified from
4 the FR notice and that is because there was a typo.
5 This is intended to reflect what is in the CFR and on
6 here it should.

7 The next set of definitions is recondition,
8 refurbish and rebuild. And so here we have restores a
9 medical device to the OEM's original specification or
10 to be like new. The device may be brought to current
11 specifications if this change does not significantly
12 change the finished device's performance or safety
13 specifications or intended use. That is to contrast
14 it with remanufacturing. And this could include the
15 repair of components, installation of certain software
16 or hardware updates that do not change the intended
17 use of the original device and replacement of worn
18 parts.

19 We received a lot of feedback that the
20 definitions we provided for recondition and refurbish
21 were too similar. So we agreed and we combined them
22 for the purposes of this workshop.

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1 In addition the original definition of
2 recondition had a piece that stated under certain
3 circumstances the device could be brought to current
4 specifications and many commenters pointed out that
5 that was ambiguous and so we inserted the second
6 bullet here to make it clear that we are trying to
7 distinguish it from remanufacturing.

8 And certainly further distinctions can be
9 made, for example we could further define like new or
10 OEM specifications, or current versus original
11 specifications. Here in particular we felt that more
12 of a discussion would be useful to make these
13 distinctions. We intentionally made this definition
14 broad so it can be usable in this workshop. And again
15 there may be many ways to break this down into a final
16 definition but that is beyond the scope of the reasons
17 we were coming up with definitions for today.

18 The next definition we have, service. We
19 view service as repair and maintenance essentially.
20 And this definition the biggest change is that we've
21 clarified that maintenance is preventative or routine.
22 So the definition we have here is repair and/or

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1 preventative maintenance of one or more parts in a
2 finished device after distribution for purposes of
3 returning it to the safety and performance
4 specifications established by the OEM and to meet its
5 original intended use. Servicing cannot change the
6 intended use of the device from its original purpose.
7 Again we are trying to distinguish this from
8 remanufacturing here. And again this is a very broad
9 term.

10 And what I'd like to point out is that
11 servicing doesn't say anything about the overall state
12 of the device. If you service a device, you may only
13 be working on a single component and/or a few
14 components. And this is in contrast with
15 refurbishing, reconditioning or rebuilding where you
16 are describing something about the state of the whole
17 device.

18 Here we have our definition for repair. And
19 it is to return a component to original specifications
20 including replacing non-working components or parts
21 outside of routine or periodic upkeep for the current
22 owner of the device. Again we don't view this as

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1 implying anything about the state of the device
2 overall. Repair work may be isolated to a particular
3 component and not consider the overall state of the
4 device. With that being said repair is one of several
5 activities that may be needed to recondition,
6 refurbish or rebuild medical devices.

7 Lastly we have remarket. This was not
8 changed from the FR Notice. And this is the act of
9 facilitating the transfer of a previously owned device
10 from one party to another by sale, donation, gift or
11 lease.

12 And I just want to remind everyone that
13 these are only working definitions for today's
14 workshop. They are not new regulatory definitions and
15 if you are using these terms in a different way than
16 we have defined them here, again, that is okay but
17 please just be clear about it.

18 So now I'd like to present some of the
19 stakeholder feedback we received in response both to
20 the FR Notice and also unsolicited feedback we've
21 received. And so first I'd like to talk about some of
22 the feedback on the importance of service quality.

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1 We've received feedback that quality service
2 maintains device conformance with specifications and
3 performance standards. Quality service resolves
4 unintended or improper device function and doesn't
5 contribute to the recurrence of these problems. And
6 lastly quality service should produce sufficient
7 information for the facility or anyone servicing the
8 device in the future to know the service history and
9 current device configuration.

10 We received lots of feedback on contributing
11 factors to quality service and I've listed some of
12 those themes here: we have quality management systems,
13 training, availability and use of quality replacement
14 parts, and access to device specific information.

15 So we received feedback that organizations
16 that have implemented a quality system may be better
17 suited to perform some of these activities. And that
18 there are certifications available that may be
19 relevant, these include ISO 9001 and ISO 13485.

20 In addition to broad comments about the
21 quality system there were examples provided and those
22 include supplier qualification and process validation

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1 and service documentation. And we think those examples
2 in particular could be related to some of the other
3 themes that were brought to our attention.

4 Another theme was training and this was that
5 service personnel should only work on those devices
6 for which they have adequate knowledge, skill,
7 training and experience. And this is really going to
8 vary. It is going to vary on the complexity of the
9 medical device. It may change between different
10 models. And it could depend on the type of service
11 needed.

12 Next we have replacement parts. There was
13 concern that low quality parts may lead to repeated or
14 additional device malfunction and the need for re-
15 service or repair of the device sooner. Some
16 stakeholders expressed concerns about the limited
17 availability of certain replacement parts.

18 And then lastly we have device specific
19 information. And so not all device specifications or
20 test procedures are publically available or able to be
21 measured with generally available test equipment and
22 that limits some people's ability to do what they

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1 believe is a quality job. And device specific
2 equipment may be needed to perform certain types of
3 service or testing.

4 And then we also just wanted to point out
5 here that manufacturers of radiation emitting
6 electronic products have additional requirements about
7 information that manufacturers have to provide that
8 don't apply to medical devices generally.

9 So to summarize we propose some working
10 definitions here. They are for clarity; they are not
11 new regulatory definitions. Some of the themes we saw
12 in the stakeholder feedback we received included the
13 importance of a quality management system, the
14 importance of proper training, the availability and
15 use of quality replacement parts, and access to device
16 specific information.

17 And in the workshop today and tomorrow we
18 hope to expand on this feedback and learn more.

19 Thank you.

20 CAPT. MITCHELL: Good morning and welcome
21 again. My name is Diane Mitchell and I am the
22 Assistant Director for Science in the Center for

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1 Devices and Radiological Health.

2 We are now going to begin the stakeholder
3 presentation section so I'm going to ask the people
4 who are presenting to come up to the table while I
5 give some housekeeping remarks.

6 So during this section each speaker is going
7 to have 15 minutes to talk and there is no Q & A
8 during this section. We actually will be timing the
9 speakers and so we have a timer up here but we also
10 have a timer in person, Astin Ross, and she has a
11 yellow card for 13 minutes and a red card for 15
12 minutes. Astin I'm going to ask you to sit a little
13 bit closer over here.

14 The speakers, I'm going to ask that when we
15 call the speakers, they do come up to the podium for
16 the presentation.

17 And if those in the back cannot hear the
18 speaker if you wouldn't mind just raising your hand
19 and that way the speaker knows that they need to do a
20 little bit of an adjustment. So thank you for that.

21 I'm going to introduce each speaker by name
22 and title but I will tell you that I have had the

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1 opportunity to read the bios and CVs of these speakers
2 and I just want to make a comment that each of these
3 speakers brings a wealth of knowledge to this
4 discussion that we will be having today.

5 So with no further ado our first speaker is
6 going to be Peter Weems. He is the Director of Policy
7 and Strategy affiliated with Medical Imaging &
8 Technology Alliance, MITA. Peter, thank you very
9 much.

10 STAKEHOLDER PRESENTERS

11 MR. WEEMS: Thank you. Good morning. My
12 name is Peter Weems. I'm with the Medical Imaging &
13 Technology Alliance, also known as MITA. We are the
14 leading trade association representing the
15 manufacturers, medical imaging equipment and radio
16 pharmaceuticals.

17 I'd like to start by thanking the Food and
18 Drug Administration for holding this public workshop
19 and for their continued engagement on the very
20 important topic of proper servicing of medical
21 devices.

22 I'd also like to thank the other

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1 stakeholders for coming together today and tomorrow to
2 discuss the issues facing the industry and how we can
3 best ensure patient safety and effective device
4 performance.

5 As manufacturers our member companies are
6 responsible for the innovation, original design,
7 manufacture, packaging, labeling, assembling and
8 upgrading of medical devices. Manufactures or OEMs
9 also often provide servicing activities for installed
10 devices both their own and those originally
11 manufactured by other companies. Whether or not the
12 OEM is also the entity which services a device it has
13 a stake in all service activities.

14 Improper servicing presents significant
15 concerns including creating challenges such as
16 difficulties in future OEM provided servicing
17 operations and the potential for significant periods
18 of downtime if poor service must be remedied,
19 difficulties in providing future field upgrades or
20 field corrections to the device if improper parts have
21 been used or if the device has otherwise been altered.
22 Lack of required regulatory reporting and incomplete

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1 device history does not allow for tracking of
2 significant events, root cause investigation or
3 prevention of adverse events. Further there are
4 concerns about voiding existing device certifications
5 such as UL certifications and liability concerns if a
6 device causes injury, damage, or other significant
7 problems.

8 Because our member companies and their
9 service departments regularly encounter these and
10 other challenges we have raised this issue with the
11 FDA several times over the past few years. In raising
12 this issue our goal is to ensure the performance of
13 these activities always results in the safe and
14 effective operation of medical devices.

15 We believe that the most efficient method
16 for ensuring this would be to extend regulatory
17 oversight including minimum quality, safety and
18 regulatory requirements to all entities which service
19 medical devices. And just to be clear when I say
20 service I mean the entire bucket of activities listed,
21 it is just shorter to say it that way than the entire
22 paragraph of things we are talking about today.

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1 Further I'd like to state right now very
2 clearly and unambiguously that it is not our position
3 that performance of these activities should be limited
4 to only the original equipment manufacturers. It is
5 not our goal to limit competition or drive anyone out
6 of business. I will repeat this later in the
7 presentation because it is true and because it is
8 something we firmly believe.

9 We recognize that many third-parties
10 including in-house hospital engineering teams,
11 Independent Service Organizations and others are
12 currently performing quality service. There is, of
13 course, the problem of right now, only service
14 activities performed by an OEM are regulated by the
15 FDA.

16 As discussed earlier non-OEM service
17 activities do not have the same oversight and are not
18 held to the same quality, safety and regulatory
19 requirements. This is an important problem because
20 performance of these activities within a quality
21 system by properly trained personnel using qualified
22 properly sourced parts greatly reduces the risk of

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1 harm to the patient or operator and greatly improves
2 the performance of the device.

3 This matters to us for two main reasons:
4 patient safety and device performance. It was because
5 of patient need that medical imaging equipment exists.
6 For this reason the patient is the most important
7 stakeholder in device servicing. Safe and effective
8 operation of medical imaging equipment allows for
9 views into anatomical structure and physiological
10 function of the patient which are otherwise impossible
11 barring surgical intervention. Patients and
12 healthcare providers count on the safe, effective and
13 reliable operation of medical devices. If medical
14 devices do not perform properly or do not perform at
15 all due to improper servicing patients may not be able
16 to receive the care they need and healthcare
17 professionals are unable to do their job effectively.

18 In general there are two main ways that harm
19 can be caused due to improper servicing: First,
20 direct bodily harm resulting from improper functioning
21 of the device due to mechanical, maintenance or
22 calibration issues such as excessive radiation from

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1 incorrectly calibrated equipment or physical injury
2 from mechanical failure. There is also the risk of
3 health care associated infections such as infections
4 resulting from improperly sealed ultrasound
5 transducers. Patients, operators, physicians and
6 anyone else in close proximity or in contact with the
7 device may be subject to this kind of harm.

8 Less noticeable however is indirect harm
9 which may result from delayed diagnosis or
10 misdiagnosis due to poor image quality. For example
11 images of non-diagnostic quality due to miscalibration
12 resulting in tumors not being visible. This kind of
13 harm is unique to diagnostic equipment including
14 medical imaging devices.

15 I will repeat patient has the most at stake
16 if the device fails to perform in a safe and effective
17 manner due to improper servicing. Patients should be
18 able to assume an equivalent level of safety and
19 efficacy regardless of service provider. Performance
20 of these activities within a quality system by
21 properly trained personnel using qualified properly
22 sourced parts greatly reduces the risk of harm to the

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1 patient.

2 So as was mentioned earlier there were a
3 number of comments received to the docket. I read all
4 of them. And I think there was a lot of very
5 interesting material there for discussion but there
6 were also a lot of misconceptions I think about the
7 manufacturer's goal and interest in this. And I would
8 like to take the opportunity to clear up a couple of
9 misconceptions.

10 First it is not our position the performance
11 of these activities should be limited to only OEMs.
12 Many third-parties including hospital service teams,
13 Independent Service Organizations and other are
14 currently performing quality service.

15 Second it is not our belief that applying
16 QSR to third-party servicers would be unduly
17 burdensome and we believe that it is a reasonable
18 expectation. The QSR is scalable meaning it applies
19 to large entities with considerable resources as well
20 as small entities with more limited resources.
21 Further certain elements of the QSR may or may not be
22 applicable depending on the nature of the activity

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1 being performed. As an example the document controls
2 element would look very different in practice for a \$1
3 billion enterprise and a \$1 million enterprise.

4 However, the same principles would apply.

5 Finally a major misconception that we'd like
6 to clear up is that we are not asking for a solution
7 to a problem that doesn't exist. We are, in fact,
8 asking for a solution to a known and ongoing problem.

9 Improper servicing unfortunately has led to
10 a number of incidents. Through public comments,
11 meetings with the FDA, MDR submission and other means
12 the device industry has submitted numerous examples of
13 improper servicing that posed serious problems for
14 patient safety and device performance.

15 Now the FDA has only given me 15 minutes to
16 speak so I can't go through all of the examples I have
17 sitting on my desk but I did bring along a couple.

18 Right here is an improper part in an
19 angiographic power injector system. This was
20 discovered during a recent service call and it was
21 observed that a third-party service vendor had
22 inappropriately substituted a wood screw, like the

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1 kind you would find at Home Depot or in a drawer in
2 your garage for what is a sophisticated very strong
3 turret. So an angiographic power injector of this
4 kind can inject fluid at pressures of up to 1200 psi
5 which is very powerful. So if this substituted wood
6 screw were to break or otherwise fail during a
7 procedure the turret would break free potentially
8 causing the turret and the connected syringe to act as
9 dangerous projectiles injuring or even killing anybody
10 in the room. Additionally this improper part could
11 cause vibrations during the injection thereby leading
12 to ancillary issues such as delay of procedure and
13 eventual diagnosis due to unexpected equipment
14 behavior.

15 Next up I have an example of an improperly
16 serviced MRI system. As you can see here there was a
17 bit of an explosion. What happened here was a third
18 party service subcontractor hired by an onsite
19 contractor was working at a customer site trouble
20 shooting an MRI system. The servicer was working in
21 the service panel on the MRI with the power on when an
22 ARC flash occurred resulting in burns to the

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1 contractor. The blast knocked him back and onto the
2 floor. Other people in the vicinity said that the
3 event sounded like an explosion. The event also
4 resulted in approximately half of the hospital losing
5 power. It is not known with total certainty what the
6 servicer was doing at the time of the event or what
7 caused the event to occur. He was going to be hooking
8 up a power monitor to the system but at what stage of
9 that process he was in is unknown. He could have been
10 checking the voltages prior to connecting the monitor
11 or performing some other trouble shooting activity.
12 It is known, however, that he did not have on his ARC
13 flash personal protector equipment or PPE at the time
14 of the event. The PPE itself would not have prevented
15 the incident of occurring but it would have prevented
16 or lessened the severity of the injuries that
17 occurred. This is an example of inadequate training
18 and non-compliance which resulted in bodily harm,
19 equipment damage and loss of power to a major medical
20 facility.

21 Here you can see an improperly service
22 nuclear medicine camera, the kind that looks at your

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1 heart. In this instance an OEM was contracted by a
2 dealer who is dealing with a customer complaint about
3 this nuclear medicine camera. The customer had been
4 using a third-party servicer which improperly serviced
5 their device and was now refusing to return and
6 correct the issue. With respect to the improper power
7 connection of the cooling system the way in which the
8 system was connected violates the manufacturer's power
9 and grounding isolation scheme potentially
10 compromising patient safety and device performance.
11 Further this issue could have lead to the detector
12 overheating and pixels failing. These modifications
13 also violate the nationally recognized test lab
14 listing of this device. This resulted in such great
15 degradation to the detector head that the customer
16 could not use the device.

17 Also with this device several pixels on the
18 camera had been masked. And what this means is that
19 when the device would have been used significant parts
20 of the heart would not have been visible on the image.
21 Also the cooling unit was improperly connected to
22 external power bypassing the systems isolated power

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1 and grounding system potentially compromising patient
2 safety and device performance. You can see that here
3 where this entire box has been disconnected and put
4 outside of the nuclear medicine camera. It is right
5 there on the floor. Obviously this is not how it is
6 supposed to be.

7 So here with the pixels when adjacent pixels
8 are removed a portion of the imaging detector is lost.
9 So portions of the heart would not be imaged meaning a
10 heart defect could go undetected by the reviewing
11 physician. When the pixel fails the system uses data
12 from adjacent pixels surrounding the failed pixel to
13 extrapolate. If two adjacent pixels are bad then the
14 system does not have a complete sampling of data. The
15 resulting image would have had a blurred spot
16 resulting in lower diagnostic quality.

17 Now as I mentioned we have a number of
18 examples and I presume that others will discuss some
19 of these examples during other presentations but I
20 think it is very important to point out that these
21 examples are not representative of the entire problem.
22 And the reason for that, the reason we cannot

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1 understand the entire scope of this problem is because
2 currently there is no requirement that every problem
3 be reported. And until that requirement exists there
4 is absolutely no way that we can understand the scope
5 of the issue and no way that we can address the issue.

6 So in conclusion it is our strong belief
7 that controls should not be voluntary. All entities
8 should be required to have an appropriately scaled
9 quality system adequate to the activity being
10 performed, meet minimum quality, safety, and
11 regulatory requirements and have proper oversight. We
12 believe that the best and most efficient method for
13 ensuring this would be for the FDA to extend currently
14 existing regulation and oversight to all entities
15 which service medical devices.

16 Thank you.

17 CAPT. MITCHELL: Thank you, Peter.

18 Our next speaker will be David Anbari, the
19 Vice President and General Manager of Mobile
20 Instrument Service and Repair, Incorporated.

21 MR. ANBARI: Good morning. And thank you
22 for the opportunity to present at today's workshop.

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1 I'm commenting on behalf of companies that
2 repair surgical equipment for healthcare providers
3 nationwide. To be clear with respect to the
4 definitions that were discussed earlier we are not
5 remanufacturers, we are not remarketers but we
6 probably fall into the other three categories.

7 Unlike most of the other presenters today
8 I'm presenting not from the perspective of a trade
9 association or an industry group. We don't have one
10 today. Instead we have a loose consortium of three of
11 the largest nationwide surgical equipment repair
12 companies in the United States.

13 We have collaborated to prepare these
14 comments. They reflect the consensus views of our
15 organizations today. We do intend down the road to
16 form an industry that can focus on education, advocacy
17 and advancement of our businesses in general.

18 So on behalf of my colleagues who happen to
19 also be my very direct competitors we'd like to share
20 our collective views with you today.

21 Like the FDA, like the device manufacturers,
22 like virtually everyone in this room and everyone

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1 watching we share a commitment to patient safety above
2 all else. That is our number one priority. And it is
3 achieved today, that patient safety is, through the
4 multi-layered regulatory scheme that exists. It
5 includes governmental oversight from the FDA, the
6 Center for Medicare and Medicaid Services; it includes
7 quasi-governmental regulation through the Joint
8 Commission and organizations like AAMI and ISO. And
9 it includes industry organizations again AAMI falls in
10 that category, so does the International Association
11 for Central Services and Materials Management who sets
12 forth guidelines for surgical equipment, the AORN and
13 physician led organizations like the Gastroenterology
14 Association. This current oversight framework is
15 ultimately what governs both what we do as independent
16 device servicers and what the manufacturers do in
17 keeping their equipment in great working condition.
18 And beyond that we all share the concern for public
19 health that it could be our loved one who is on the
20 table and we want to ensure that the equipment works
21 properly.

22 So much like OEMs we have invested heavily

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1 in quality management systems. With each maintenance
2 or repair event that takes place we ensure the device
3 works the way it was originally intended to. And
4 according to the data we are both doing a pretty good
5 job, both the OEMs and the independent service
6 organizations.

7 The first point of control with respect to
8 the use of a device and ensuring that it works
9 correctly is the clinical staff in a provider
10 organization who tests the device prior to its use in
11 a surgical procedure. Regardless of whether an ISO or
12 manufacturer performs service it is that test and that
13 review process prior to the use of a device that
14 ensures nothing gets used on a patient unless it is
15 truly patient ready.

16 But more according to a recent survey that
17 was update by ECRI we are both doing a good job
18 because there are very, very few reported incidents of
19 failure of devices that results in an adverse patient
20 outcome over the past ten years worth of data that
21 they searched. We're talking about 96 out of yearly
22 2.1 million reports that they looked at of adverse

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1 impacts with less than .005 percent incidents. And
2 that doesn't account for the hundreds of millions of
3 devices that we repair successfully both OEMs and ISOs
4 every year. But more importantly in these numbers
5 there is no statistical difference between the
6 performance of ISOs or OEMs in terms of adverse impact
7 to patients. We are both doing an effective job.

8 So at this point our belief is that there is
9 really no evidence to support that there is a problem
10 here that needs to be solved. And thousands of
11 provider organizations, hospitals, surgery centers,
12 doctors' offices and clinics vote every single day by
13 continuing to use our independent services that that
14 is their preferred method of obtaining service and
15 repair on their surgical equipment.

16 We think it is important for you to
17 understand why they make that choice and why patient
18 safety would be compromised if they were to choose
19 differently. So our industry maintains tens of
20 millions of surgical devices annually, devices that
21 are critical to healing patients and used by surgeons
22 every single day. These devices include stainless

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1 steel instruments, laparoscopic minimally invasive
2 surgical instruments, powered surgical equipment, both
3 rigid and flexible endoscopes and case carts that are
4 used for the transport of equipment throughout the OR
5 and central sterile processing departments.

6 One highly unique aspect of our service is
7 that we deliver most of our services on location at
8 the hospital's physical facility. We bring fully
9 equipped mobile service labs right to the hospital's
10 door and we provide convenient local expert access to
11 our health care solutions. This minimizes the
12 downtime for the equipment in the OR and our proximity
13 to end users gives us a unique ability to help those
14 end users improve the way that they care for and the
15 way that they handle those devices on a daily basis.
16 That results in reduced damage to that equipment and
17 making it more patient ready on a daily basis. It
18 enables us to be proactive in providing preventative
19 maintenance services; services that avoid failures of
20 the device when it is in the operating room. When we
21 detect a dull, damaged or misaligned device we can
22 correct it before it ever reaches a surgeon's hands.

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1 We thus help improve patient safety by ensuring that
2 the OEM's devices work correctly each and every time.

3 Another critical aspect of our service is
4 that we make it easy to maintain equipment through
5 this on-location approach to service. Because we
6 service devices from hundreds of different
7 manufacturers the hospital can contract with one
8 provider to ensure that all of its equipment is
9 maintained properly. This significantly streamlines
10 their operations, reduces their costs and makes
11 preventative maintenance more accessible. The
12 alternative would be contracting with literally
13 hundreds of device manufacturers for direct service
14 resulting in significant disruption to their
15 operations.

16 With patient safety at the top of mind we
17 help OEMs ensure that their equipment is always
18 patient ready. And that is why we employ quality
19 management systems. The basis for our quality
20 management industry wide is to return a device to its
21 original operating condition. We do not modify
22 devices as a part of our service. So all of the

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1 advantages that are inherent in the manufacturer's
2 quality systems, manufacturing processes, et cetera,
3 those are all retained in the device post service.

4 To achieve this we think it comes to three
5 key components. First off training; much like
6 manufacturers we operate training programs that use
7 apprenticeship based training and often times include
8 individuals who have been employees of or contractors
9 for device manufacturers in their prior careers. It
10 also includes clinicians, so we are able to bring an
11 actual end-user experience and end-user perspective to
12 the maintenance of these devices.

13 Secondly, we source only new, unused parts
14 and components from a robust global marketplace. With
15 today's technology we can safety ensure that a
16 component is an exact match for the OEM's component
17 using the exact same type of materials as the OEM
18 used.

19 And finally we quality check every single
20 device against specifications or measurements that
21 we've taken off of a new unused manufacturer's device.
22 We incorporate these multiple quality checks

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1 throughout our repair process so that we detect any
2 deficiency in a repair or any abnormality in the
3 device prior to its completion. We also check the
4 device as a final quality assurance check to ensure
5 that it operates to its original approved
6 specification. In some cases the quality checks that
7 we apply are greater than those that manufacturers
8 themselves apply. A manufacturer assumes that their
9 parts employed by their technician is going to result
10 in a proper repair. We have to go above that standard
11 and test final device in a semi clinical setting so
12 that we can ensure it operates the way it is supposed.
13 As evidence of these quality management systems most
14 of our firms, if not all, are certified to ISO
15 standards, in some cases we are certified to multiple
16 standards. It is the same reason that we are granted
17 liability insurance and make that investment the same
18 as what manufacturers do for those never sentinel
19 events. Despite these investments some manufacturers
20 continue to argue that only they can complete a repair
21 effectively.

22 In the comments provided by the device

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1 manufacturers and I'm certain we'll see more of them
2 today you'll see photographs of damaged equipment
3 that's been repaired improperly. These are anecdotal
4 examples; they don't reflect the tens of thousands of
5 repairs that are affected properly. Like OEMs we have
6 a file cabinet at every one of our companies loaded
7 with photographs of repairs that were completed
8 improperly, either deliberately or as a band-aid in an
9 effort to rush a device back to the operating room so
10 that a case could be completed.

11 We've included in those examples devices
12 that were repaired by manufacturers exclusively and
13 when they came to us they had failed for various
14 reasons: wear and tear and parts or through their
15 just normal use of the device.

16 So one could argue if we are already doing
17 these things, if we are already implementing quality
18 systems and we're already doing a good job what is the
19 risk of FDA oversight? And we feel that the answer to
20 that question lies in our value to our customers. Our
21 industry is typically thought of as repair guys
22 because that is our heritage for over four decades of

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1 consistent service. But today we deliver tens of
2 thousands of hours of consulting, training and
3 advisory services to healthcare professionals
4 nationwide. Our education programs are proactive,
5 they help providers reduce damage to equipment before
6 they create it thus bringing down their cost for
7 repairs but also providing better patient care and
8 improving the readiness of those devices in the
9 operating room.

10 Through our equipment expertise we help
11 ensure compliance with the manufacturer's instructions
12 for use and multi-society guidelines with respect to
13 how devices are to be used and reprocessed. And in
14 cases where manufacturer has changed the design of a
15 device or changed the instructions for use of a device
16 or how it is to be reprocessed we help educate the
17 industry, the healthcare providers and individuals
18 that support them on how those changes impact them and
19 how they can ensure compliance.

20 In many ways we are helping manufacturers
21 ensure that devices are used and reprocessed as
22 intended.

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1 My company, speaking on my behalf, has
2 attempted to forge partnerships with a number of
3 manufacturers over our time period. We've had various
4 levels of success with that but none of them has
5 endured the test of time largely because our
6 commercial interests and their commercial conflict at
7 some point.

8 The biggest benefit that providers do see
9 from working with Independent Service Organizations is
10 clearly financial. By reducing repairs and helping
11 them learn how to not damage their equipment we
12 significantly can reduce their spend on repairs. At
13 the same time we help improve the efficiency of their
14 operating room.

15 And with the advent of the Affordable Care
16 Act and pressure on the financial performance of
17 provider organizations being able to help them improve
18 efficiency and drive top line revenue is of top mind
19 concern.

20 We help extend the useful life of devices
21 which helps them avoid premature replacement; it is an
22 area where we simply aren't aligned with most

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1 equipment manufacturers who are incented to drive the
2 sales of their devices. We can dramatically impact
3 the replacement of devices through preventative
4 maintenance, through proper repairs but also by
5 maintaining perfectly good equipment that's been
6 declared obsolete by a manufacturer. So we still
7 maintain devices that are no longer maintained by
8 manufacturers simply because they've upgraded the
9 technology.

10 Most providers that we work with choose to
11 invest a portion of the savings that we help them
12 achieve on repairs and in reduced replacement spend to
13 invest in better and more proactive preventative
14 maintenance programs. That helps them avoid future
15 failures in the operating room and helps improve
16 patient safety.

17 And again the local presence of our people
18 on a national scale helps promote routine maintenance
19 that would otherwise be nearly impossible for a
20 manufacturer to deliver at the scale that we do.

21 What concerns us as an industry is with
22 these clear benefits and evident benefits from what we

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1 do there is no evidence of a quality problem, why
2 raise the cost? Why implement a regulatory system or
3 oversight system that would potentially degrade any of
4 these benefits that we provide with no clear
5 indication of a benefit?

6 We believe the key is for the FDA and others
7 to promote a robust marketplace that offers providers
8 choices. The robust market for Independent Service
9 Organization regulates itself. First off poorly
10 designed devices, devices that don't function that are
11 manufactured by a manufacturer are quickly removed
12 from the market. Independent Service Organizations
13 that don't do an effective job repairing on a
14 consistent basis or servicing on a consistent basis
15 they're driven from business. This happens because
16 providers have a choice when they choose where to
17 source repairs. And most importantly the multi-
18 layered oversight structure that exists today with
19 government, quasi-government, and trade associations
20 and industry groups provides more than sufficient
21 oversight and guidelines to direct healthcare
22 providers. It is the strength of the market and

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1 existing oversight framework that ensures patient
2 safety and is the reason we see as strong performance
3 as we do as evidenced in the ECRI study.

4 So the question becomes how can the FDA help
5 the industry as a whole advance. We believe the
6 answer does lie in cooperation. It involves promoting
7 cooperation with OEMs and other service organizations
8 while protecting the confidential information of both
9 entities. It involves making parts and service
10 information available to everyone that works on these
11 devices. It involves ending the prospect or ending
12 bundling of sales of capital equipment with
13 maintenance contracts which can result in predatory
14 pricing that does nothing more than drives down
15 competition. It involves removing unnecessary locks
16 and technology that are placed in devices today that
17 do nothing to serve the actual use of the device in
18 its clinical efficacy and instead simply serves to
19 block third party organizations from being able to
20 access the device. In the extreme it could involve
21 promoting manufacturers working directly with and
22 certifying third party organizations.

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1 But the current multi-layered regulatory
2 framework provides adequate oversight. The answer is
3 thus not in regulating the market but it is in guiding
4 the market and not losing track of the advantages that
5 I've discussed today.

6 We shouldn't put the risk to benefits of
7 that local responsive service being able to handle
8 repairs from multiple manufacturers' devices, helping
9 control capital spending and avoid premature failure
10 of devices and premature and unnecessary replacement
11 of devices and ensuring that the critical advice and
12 advocacy that we bring to healthcare organizations on
13 a day-to-day basis nationwide doesn't end. Losing
14 these benefits is not automatic but there are often
15 unintended consequences of oversight and regulation
16 that limits competition in the marketplace.

17 Considering that there is no clear evidence
18 of a difference between the performance of reputable
19 service organizations, independents and manufacturers
20 we believe the risks are too great. And the fact is
21 that it remains the potential for a de facto OEM
22 monopoly with respect the service of their devices in

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1 the extreme.

2 The greater risk to patient safety is to
3 eliminate all of the good things that we bring to
4 healthcare providers who choose to work with our
5 organizations on a daily basis to lose those to the
6 unintended consequences of regulation. So on behalf
7 of the companies that I work with and compete with on
8 a daily basis we support patient safety and we also
9 support cost efficiency in the marketplace.

10 Thank you very much for your time.

11 MS. MITHCELL: Thank you, David.

12 Tara Federici, the Vice President of
13 Technology and Regulatory Affairs from AdvaMed will
14 now speak.

15 MS. FEDERICI: Thank you. Good morning. My
16 name is Tara Federici. I'm the Vice President of
17 Technology and Regulatory Affairs at AdvaMed.

18 AdvaMed advocates for a legal and regulatory
19 environment that advances health care by assuring
20 patient access to safe and effective devices.

21 By way of explanation in my comments today
22 I'll be using the term servicing to broadly refer to

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1 all of the R words that we're focused on here today.

2 OEMs are mandated by FDA to design their
3 devices under strict quality system regulation
4 requirements to ensure their safe and effective use.
5 The QSR requirements were establishes by the Safe
6 Medical Devices Act of 1990 after a lengthy
7 congressional investigation into device safety issues.
8 When the quality system rule was implemented as we've
9 already heard third-party service providers were
10 exempted from the same level of regulation and
11 scrutiny. As a result patients and providers my
12 falsely believe all devices are as safe and effective
13 as the OEMs are capable of making them. I would note
14 that since the passage of SMDA 26 years ago many
15 devices have become significantly more complex.

16 AdvaMed's members manufacture and may
17 service their own devices and some may also act as
18 third-party service providers for devices made by
19 other companies. Many OEMs publish service manuals or
20 make them available for sale to biomedical technicians
21 at healthcare facilities and to other third parties
22 and they may similarly make their replacement parts

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1 available. OEMs may also offer training to third
2 party entities to service their equipment. Other OEMs
3 may service their own equipment and may not make
4 manuals or copyrighted parts available as this could
5 disclose trade secret information to competitors. In
6 short are companies who use a variety of business
7 approaches and models all of which are appropriate and
8 are designed to ensure that products are safe and
9 effective for patients.

10 AdvaMed has three overriding concerns
11 relating to the safe and effective performance of
12 devices and third-party repair. First device repairs
13 are being performed by untrained personnel who may not
14 be using the necessary specialized equipment, are
15 performing the needed calibration and testing to
16 ensure that the product is safe and effective before
17 it is returned to use. Second, device replacement
18 parts or components of unknown provenance such as
19 those cannibalized from non-functional equipment or
20 manufactured by third-party entities claiming OEM
21 device compatibility are being used in the repair of
22 devices. Use of these defective parts can result in

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1 adulterated devices. Last, device repairs are being
2 performed without required compliance with core
3 servicing standards to which OEMs are held under the
4 QSR. Standards which AdvaMed believes are essential
5 for the safety and efficacy of medical devices.

6 That said we believe many third-parties
7 already meet many of the key elements of the QSR
8 because they understand the benefits of implementing a
9 quality system both for their business and for
10 patients. Importantly the QSR is risk based and
11 scalable. It applies to all device manufacturers no
12 matter their size from the very smallest device
13 manufacturers with a handful of employees to the very
14 largest. Patients have the most to lose if devices
15 fail to perform safely and effectively. And all three
16 of the situations I just mentioned can significantly
17 impact patient safety.

18 Although some have argued there is no
19 evidence of unsafe devices related to third-party
20 repair, over the course of just three years AdvaMed
21 has become aware of at least 137 MDRs for just three
22 device categories. This is despite the fact that many

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1 OEMs do not currently report MDRs associated with
2 third-party repair and that it is difficult for OEMs
3 to detect problems related to third-party repair.
4 Because third parties are not required to mark the
5 devices they service or to identify the components
6 they use the end user may not know that the failed
7 device was serviced by a third party.

8 In addition third parties are not required
9 to submit MDRs. As a result all the reportable events
10 are associated with the OEM rather than the third
11 party. Another reason that MDRs associated with third
12 parties are low. Often the use of non-OEM parts or
13 unauthorized repairs is discovered serendipitously by
14 the OEM. A common scenario is that a device has a
15 difficult to repair failure and is sent to the OEM for
16 repair. Once at the OEM site the OEM discovers
17 mismatched serial number parts or internal forensics
18 logs would show unauthorized repair.

19 For all these reasons adverse events related
20 to the use of non-OEM parts or repairs by third
21 parties are going unnoticed and uncounted. AdvaMed's
22 member companies have assessed the risks associated

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1 with third party repair and found increased safety and
2 performance failures due to devices being modified or
3 used in unapproved configurations. If non-validated
4 parts or configurations are added to a device the
5 previously validated performance of the device now
6 becomes unknown. This can impact the safe use of the
7 device. Products which are altered from what was
8 initially cleared or approved may be considered
9 adulterated under FDA's current regulations.

10 Third party activities can also cause other
11 intended consequences. Examples include non-valid
12 interactions between hardware timing circuits and
13 software or firmware timing responses in devices in
14 unapproved OEM configurations. These unapproved
15 configurations can result when substituting parts from
16 one OEM approved and tested device into a different
17 OEM approved and tested device.

18 Some third party repairs may allow a device
19 to pass functional testing and operate normally in a
20 nominal mode. However, when the device is stressed to
21 it edge conditions the unapproved configurations can
22 result in unpredictable device behavior.

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1 OEMs and OEM qualified servicers are aware
2 of all updates and product changes and test the
3 devices according to current specifications using
4 validated processes. As a result OEMs and their
5 qualified partners are more equipped to limit the
6 risks associated with service. Importantly as
7 required by the QSR the OEM has the most current
8 device master record which is linked to the original
9 documentation in the design history file. Information
10 about reliability is needed to make decisions for what
11 should be replaced when the device is being serviced
12 and to understand the expected life of the device.

13 In contrast, third parties have no
14 requirement to analyze service reports with
15 appropriate statistical methodologies to determine
16 when events need to be reported and then to actually
17 report them to FDA. This adversely affects public
18 health as it prevents both the OEM and FDA from having
19 important information about device performance issues
20 that could require a correction or a removal.

21 By comparison OEM technicians conduct
22 repairs using documents written by the device's design

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1 engineers and use tools created by the design team.
2 Third parties may not be using the latest
3 documentation and may have to rely on trial and error
4 for product repair. OEM technicians frequently repair
5 many of the same items per day while third parties may
6 have limited exposure to many different types of
7 devices.

8 Some OEM products require in excess of 90
9 custom tools along with a custom programmer. It is
10 not clear how third parties are disassembling or
11 reassembling these products and what impact the use of
12 non-custom tools has on device performance and safety.

13 For these reasons AdvaMed believes repair of
14 devices whether performed by OEMs or third parties
15 should be subject to FDA regulation and oversight by
16 key elements of the QSR.

17 As I mentioned earlier the QSR is scalable
18 and risk based thus certain elements of the QSR may
19 not be applicable to third parties depending on the
20 nature of the activity they are performing.

21 AdvaMed outlined the key elements of the QSR
22 we believe apply to third party repair in our docket

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1 comments. However briefly at a high level we believe
2 third parties should obtain training related to the
3 level of repair they are performing, have access to
4 proper OEM approved equipment, components and service
5 manuals related to the level of repair they are
6 performing, establish processes to control purchasing
7 of qualified components and maintain device history
8 records for repairs, inspection and testing. In
9 general third parties that are OEM qualified would
10 have access to all the elements I just mentioned.

11 In closing OEMs are already subject to and
12 meeting all of the requirements of the QSR to ensure
13 the safety and effectiveness of devices for patients
14 and users alike. Notably if an OEM used parts from an
15 unauthorized supplier or relied on untrained personnel
16 for repair the affected devices could be considered
17 adulterated and could be subject to field action. But
18 third parties continue not to be subject to QSR
19 potentially imperils patient and users. It seems to
20 us that QSR requirements in the safety and
21 effectiveness of devices is equally applicable to
22 third-party repair thus ensuring the safety and

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1 effectiveness of devices for users and patients.

2 Thank you for the opportunity to share our
3 views on this topic.

4 CAPT. MITCHELL: Our next speaker will be
5 Barbara Maguire, the Vice President, Quality and
6 Geisinger Clinical Engineering ISS solutions.

7 Now before Barbara speaks I'll just give you
8 a heads up that we will be taking a break just before
9 ten o'clock for 15 minutes for planning purposes.

10 MS. MCGUIRE: Good morning. My name is
11 Barbara McGuire and on behalf of the American College
12 of Clinical Engineering I would like to thank the FDA
13 for this opportunity to present the viewpoint of the
14 clinical engineering community on this very important
15 topic.

16 Numerous colleagues from ACCE have
17 contributed to this presentation and I'd like to
18 particularly thank Malcolm Ridgway, Alan Lipschultz
19 and Mark Bruley for their contributions.

20 I'm here today representing the ACCE
21 viewpoint. I currently work as Vice President of
22 Quality at ISS Solutions. We are owned by Geisinger

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1 Health System. We provide clinical engineering and IT
2 services to both healthcare and non-healthcare
3 clients. Geisinger Health System is also our largest
4 client in clinical engineering. So I have the unique
5 position of running an in-house clinical engineering
6 service at Geisinger Health System and then also
7 overseeing the quality of the services that we provide
8 as an ISO to our clients outside of Geisinger.

9 We've partnered successfully with many of
10 the manufacturers who are represented here in this
11 room and we think that is an important part of the
12 services that we provide to patients. We invest a lot
13 of time and resources into ensuring that the services
14 we provide are of the highest quality.

15 As I said I'm representing ACCE today so I
16 just wanted to briefly mention the mission of the ACCE
17 is to establish a standard of confidence and promote
18 excellence in the clinical engineering practice and to
19 promote the safe and effective application of science
20 and technology in patient care. So we represent just
21 over 750 members and we've been around since 1990.

22 I wanted to start out by noting one of the

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1 FDA's priorities is to use real world evidence in
2 making regulatory decision making. So that is what
3 ACCE attempted to do in their presentation is to point
4 out this real world evidence.

5 With respect to the additional regulation of
6 servicers the position of ACCE is that the vast
7 majority of servicers are already regulated mainly
8 through CMS as well as through other agencies. And
9 that third parties as well who are working within the
10 healthcare organizations are also as a secondary
11 measure subject to the same regulations by the
12 healthcare organizations that they work for.

13 So for example we have a laser service
14 company that we use extensively and they readily
15 provide to us the credentials for their servicers,
16 documentation that they inspect to manufacturer's
17 guidelines. And we ask for the same information from
18 any company who is servicing critical equipment at our
19 facilities. We also review the credentials and
20 quality programs for all vendors who come on site or
21 who work on our equipment. And we expect them to have
22 this program in place.

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1 Thirdly it is the ACCE's position that
2 additional regulation would be redundant and even
3 counterproductive to providing the highest level of
4 patient safety.

5 There are three basic reasons for the ACCE's
6 position. One related to the real world evidence is
7 that since this is the FDA's own standard for decision
8 making we think this is the most important and no
9 evidence has been presented showing significant
10 patient safety issues related to equipment service.

11 There are also many possible downsides to
12 additional regulation. Likely downsides include
13 higher cost for healthcare institutions; elimination
14 of some in-house and third-party servicers due to this
15 additional burden; and this would decrease competition
16 and decrease the choices available to healthcare
17 organizations.

18 Some of the arguments that have been
19 proposed in support of added regulation we feel are
20 not topics under jurisdiction of the FDA and these are
21 arguments such as increasing fair trade and correcting
22 a liability imbalance.

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1 First I'll address the issue of the real
2 world evidence. Here we are looking for statistics,
3 not just anecdotal evidence. So despite the small
4 number of anecdotal reports we feel that there is an
5 insufficient level of evidence of service related
6 incidents to justify any additional regulation. The
7 primary body of this evidence are the seven studies
8 listed here. So notably there is one from the UK,
9 their Medicines and Health Care Products Regulatory
10 Agency which is an executive agency of their
11 Department of Health. And when they classify the
12 primary cause they found that improved maintenance was
13 tenth on the list of causes after much more common
14 ones related to the design of equipment, labeling,
15 packaging, improved QA.

16 The 2012 study done by the Joint Commission
17 reviewed 1526 responses and found none that were
18 related to maintenance omissions. There was also a
19 2013 analysis of sentinel event data covering the
20 period 2004 to 2011 and showed that the sentinel
21 events caused by maintenance omissions were between
22 0.14 to 0.74 per million.

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1 And in 2014 Aramark data was presented over
2 a ten year period which was analyzed and showed only
3 six incidents traced back to maintenance. And these
4 were spread across stakeholders and did not show a
5 higher incidence from third-party servicers.

6 Details of all these studies will be covered
7 as well in later panels and were also included in the
8 ACCE's docket comments.

9 I wanted to note though the two studies done
10 by ECRI which actually showed a decrease since this
11 issue was last looked at in 1998. The review
12 completed in 1998 demonstrated less than a quarter of
13 one percent incident of service related patient issue.
14 They recently repeated a similar analysis and the data
15 showed a decrease to .005 percent.

16 Many have pointed out that the low incidence
17 may be due to significant underreporting. But we feel
18 that there are already sufficient requirements for
19 reporting under the SMDA and FDA regulations which
20 require user facilities to report incidents. OEMs are
21 also required by 21 CFR to report malfunctions of a
22 device that would be likely to cause or contribute to

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1 death or serious injury.

2 Even if we assume there is significant
3 underreporting if the incidence were doubled it would
4 not be significant enough to warrant action from the
5 FDA.

6 However, there are opportunities for
7 improving reporting such as getting buy-in from the
8 different sector organizations to try to encourage
9 further reporting to address this.

10 We could forge a consensus on what should be
11 reported; better standardize the format of reporting
12 and the method, identify who should receive the
13 reports to ensure that confidentiality is preserved
14 and look at how to analyze as the overall data and
15 statistics on an industry wide basis so that we are
16 all working with the same information.

17 The second part I'd like to address are the
18 likely downsides due to added regulation. So the
19 additional regulation would certainly increase the
20 cost of onsite service. This may result in reduced
21 levels of onsite service which could cause delays in
22 repairing of devices and therefore delayed patient

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1 care. Higher hospital expenses would reduce capital
2 that would be available to acquire additional devices.
3 And reduced onsite support would also reduce other
4 safety enhancing services that are currently provided
5 by those onsite resources.

6 So the overall effect would be to increase
7 hospital costs and therefore increase the cost of
8 health care. Some organizations could comply but
9 their costs would still increase. Even if they are
10 meeting the existing requirements it would mean
11 another registration, another set of audits and some
12 would not be able to bear the cost of this and would
13 cease to function.

14 So why is this so important? The value of
15 onsite technical support really enhances patient care.
16 There is faster response time by having individuals
17 who are right there onsite with the clinicians. The
18 people onsite are best able to troubleshoot systems of
19 multiple devices that might come from multiple
20 manufacturers. They provide support for clinical
21 staff even during procedures. They can work on
22 integrating equipment from multiple stakeholders.

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1 Onsite servicers can also provide ongoing training for
2 clinical staff and input into systemic improvements
3 that would prevent further incidents. Onsite staff
4 can also provide input into capital planning to
5 encourage standardization and efficiency down the
6 road.

7 Addressing the third point that some of the
8 issues are outside the jurisdiction of the FDA. The
9 issue of the uneven playing field we feel is a
10 complaint or issue that belongs in the purview of the
11 FTC instead. And the liability imbalance is a
12 judicial issue that should not be addressed here.

13 There are many issues which differentiate
14 the environment in which the manufacturers and third-
15 party servicers must function in; mainly that we
16 already must comply with CMS, Department of Health,
17 and local regulatory inspection requirements. The
18 fact that we are exempt from one regulation that the
19 manufacturers are subject to is not by itself a reason
20 to impose that on onsite servicers.

21 In summary additional regulation of
22 servicers would be redundant and the evidence does not

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1 show that patient safety would be improved. There is
2 no real world evidence of significant level of
3 problems. There is no prospect of significant
4 benefits from added regulation, and the potential
5 downsides are significant including the increasing
6 cost of health care.

7 Instead our recommendations are that the FDA
8 continue to work to encourage collaboration from the
9 manufacturers and the onsite servicers including
10 things like education and training, and encourage more
11 community based initiatives such as these that many of
12 the manufacturers and stakeholders are already
13 involved in successfully. And this involves efforts
14 to standardize maintenance documentation, to work on
15 interoperability between various devices, and to
16 encourage further voluntary reporting so that there is
17 no concern about missing evidence.

18 Also to encourage manufacturers to provide
19 better support to users after the sale we feel as
20 clinical engineers that that would be the single most
21 significant improvement that we'd like to see that
22 would help us to improve patient safety. If we have

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1 access to good documentation at the same level that
2 the manufacturers provide to their own servicers,
3 access to parts, and access to training that that
4 would really help to improve patient care.

5 So we'd like the FDA to encourage ongoing
6 collaboration between manufacturers and the healthcare
7 technology management community and not to impose
8 additional regulations on third-party servicers.

9 I thank you for your attention.

10 CAPT. MITCHELL: Thank you, Barbara.

11 We will now be hearing from Robert Kerwin,
12 General Counsel from the International Association of
13 Medical Equipment Remarketers and Servicers [IAMERS].

14 MR. KERWIN: Thank you. I'm the last
15 speaker before your break. I'm only grateful I'm not
16 the last speaker before lunch. So, yes, my name is
17 Robert Kerwin on behalf of the International
18 Association of Medical Equipment Remarketers and
19 Servicers for which it has by my privilege to serve as
20 General Counsel for 20 years.

21 We wish to thank the FDA for this
22 opportunity to participate in a workshop and as with

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1 the prior speaker we hope there will be future
2 opportunities for workshops of this type and
3 collaboration and that the FDA consider this type of
4 engagement well into the future for all stakeholders.

5 Because our association name is a little
6 long I'll be referring to it as we refer to it as
7 IAMERS. A few words about IAMERS, for almost 24 years
8 now IAMERS has been the leading voice of secondary
9 diagnostic imaging marketplace. All IAMERS members
10 are diagnostic imaging industry members. We note this
11 as there are some companies here today who focus on
12 the sale and service of endoscopic devices. The
13 imaging modality of IAMERS members are MRI, CT,
14 ultrasound, nuclear medicine and general radiography.
15 IAMERS members include original equipment
16 manufacturers such as GE, Siemens, Toshiba, and
17 Philips. The majority of IAMERS members are made up
18 of small independents including servicers, re-
19 conditioners of systems and parts, re-manufacturers
20 and brokers. Many are alumni of OEMs and have started
21 their own businesses.

22 In 1993 IAMERS was founded to encourage

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1 adherence to the highest standards of ethics and
2 professional practice, to fulfill the demand for used
3 and refurbished medical equipment. We've been busy
4 these last 23 years. Among the things which separate
5 us from other organizations is that we require our
6 members to adhere to a code of ethics. This just
7 isn't lip service. If a complaint is raised by a
8 hospital or group medical practice or other IAMERS
9 members the complaint is considered by the ethics
10 committee. Adverse determinations have resulted in
11 very public reprimands or expulsions. No member is
12 excluded from this requirement.

13 We maintain a robust educational agenda for
14 our members which occurs at every meeting we have. In
15 the past we've conducted programs on FDA inspections,
16 UDI [Unique Device Identifier] requirements, reporting
17 of adverse events and many other areas which impact
18 our members and we were fortunate to have Mr. Benesch
19 participate and we've been fortunate to have Mark
20 Leahey participate and many other important
21 representatives of the industry.

22 Our president Diana Upton has traveled the

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1 country encouraging our members to pursue best
2 practices and ISO compliance certification. We've
3 been fortunate to have as we mentioned the FDA
4 participate in our annual meetings and programs. We
5 hope the FDA will continue to participate.

6 We've also been fortunate to have other
7 contributors from the Center for Medicaid, Medicare
8 and Medicaid devices, the Department of Commerce,
9 other original equipment manufacturers. IAMERS has a
10 proud tradition of education and outreach and we wish
11 to do more.

12 At our annual meeting in May of this past
13 year our members adopted recommendations for best
14 practices on meeting customer requirements and patient
15 safety. All members are expected to employ quality
16 management in their organizational structure,
17 policies, procedures, processes and records. Quality
18 management will be adopted regardless of whether the
19 member is a broker, servicer, remanufacturer, re-
20 conditioner or original equipment manufacturer. These
21 recommendations were unanimously adopted at the
22 suggestion of the IAMERS best practices committee both

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1 here and with our European members. The committee had
2 recommended it as a diverse group who had reviewed
3 quality objectives, quality policy inventory
4 management, customer complaints and data management.
5 And of course there is more work to be done.

6 In a recent meeting with FDA we discussed
7 IAMERS concerns and also IAMERS recommendations and
8 frankly we welcome further suggestions to the extent
9 the FDA has them.

10 IAMERS members are committed to quality.
11 IAMERS members represent viable solutions for
12 hospitals, group medical practices and other
13 healthcare providers. Indeed IAMERS believes it meets
14 or exceeds the service expectations of the imagining
15 centers they serve. Not only do our members live
16 where they often provide the service but they service
17 geographic areas underserved by other OEMs including
18 rural America. IAMERS subscribes to a big tent
19 theory. If you are a medical imaging company and
20 committed to quality and comply with IAMERS standards
21 you will be welcome as a member.

22 Pre-owned doesn't mean safety concerns. In

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1 2009 the FDA issued in response to an IAMERS request a
2 letter to advise as to what post-market adverse events
3 had been submitted to the FDA associated with
4 refurbished or remarketed devices. Though a diligent
5 search was conducted at the FDA's official records for
6 Fiscal Years 2007 to 2008 which included I am told
7 400,000 reports related devices; that search revealed
8 no pattern of adverse events or incidents indicating
9 that refurbished or remarketed devices have been
10 associated with or contributed to a death, serious
11 injury, or malfunction. We have no reason to believe
12 that this has changed in the ensuing years.

13 It may prove convenient for some to show
14 pictures of equipment without attribution,
15 unattributed except to nameless independents and to
16 suggest that certain levels of uneven performance are
17 being implemented and to claim that minimum
18 requirements are not being met. Although convenient
19 to use such anecdotal evidence in a market that
20 demands exactitude and quantification we find such
21 supposed evidence less than helpful as well as a
22 resolution of whatever concerns. We are confident the

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1 FDA will not regulate by anecdote.

2 Not every healthcare provider is in a
3 position to purchase new equipment. IAMERS members
4 provide important options for healthcare providers in
5 a marketplace where revenue is not keeping track with
6 growing costs. Purchasing from an IAMERS member is a
7 safe solution for equipment, parts, and service.
8 Independent sellers and servicers who are IAMERS
9 members are often as mentioned alumni from OEMs and
10 operate successful small businesses. They enjoy a
11 strong reputation in diagnostic imaging. And how do
12 we know this? We know this because the OEMs
13 themselves use IAMERS members. It is common for an
14 OEM to contract with IAMERS members for the supply and
15 parts as well as service as well as assisting in the
16 installing, uninstalling, transporting and storing of
17 equipment. It is therefore important to note that the
18 greatest outlet for equipment taken in trade by the
19 OEMs appears to us to be IAMERS members involved in
20 the secondary equipment.

21 Notwithstanding our strong reputation at
22 MITA's request for more regulation seems to exist as

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1 Mr. Weems has indicated MITA has meet with the FDA
2 since 2014 to express concerns about levels of
3 performance. In an August 5, 2015, a MITA PowerPoint
4 that we obtained in a FOIA request MITA acknowledged
5 that there is greater pressure on hospitals to drive
6 cross training and therefore a greater opportunity for
7 alternative service providers; that would be IAMERS
8 members. MITA advocated that all service providers
9 should register with the FDA as they have advocated
10 here today. That is not something I recall hearing
11 when IAMERS met with MITA two days earlier to discuss
12 the situation and to discuss in general our interest
13 in collaboration.

14 I note they say not to polarize but we seek
15 collaboration. The section of the PowerPoint entitled
16 examples is, however, blank. We were pleased,
17 therefore, to observe MITA's submission that it is
18 impossible to provide a statistically valid analysis
19 of the extent of the problems.

20 Our members have reminded me several times
21 including today we service better unless of course
22 AIAT information is not readily provided. We could

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1 show cannibalized equipment from devices that had been
2 worked on by independents. We've declined to do so.
3 As mentioned OEM members frequently rely on IAMERS
4 members to fulfill their contractual obligations and
5 that speaks loudly in the marketplace.

6 Query then if the IAMERS member is working
7 independently for healthcare providers on service
8 calls and later in the week at the request of the OEM
9 assisting the OEM's own healthcare provider
10 relationships is it really appropriate to now claim a
11 lack of uniform performance. OEMs frequently, indeed
12 very frequently, purchase parts from IAMERS members.

13 So I submit IAMERS members are necessary and
14 important contributors to the healthcare ecosystem and
15 no one knows it better than the OEMs.

16 We are confident that the FDA will not
17 regulate by anecdote and hope the FDA and the attorney
18 from the FTC who are present here today will recognize
19 that there may possibly, possibly be something more
20 afoot than claims of uniform performance. The
21 motivation may well have competitive origins.

22 So let's look at the market snapshot. One

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1 industry study has reported that in 2014 General
2 Electric, Philips, Siemens accounted for 70% of the
3 diagnostic imaging system market. That study also
4 reported that in 2014 original equipment manufacturers
5 including all other OEMs accounted for all by 9.7% of
6 the diagnostic imaging system revenue market shares.
7 We are concerned that healthcare providers may down
8 the road if further regulations and further activities
9 take place see fewer options and reluctantly be pushed
10 to buy new equipment when that may not be the
11 appropriate decision for their organization. As we've
12 noted not every hospital group practice can afford new
13 equipment. And the presence and success of secondary
14 service providers is essential to the marketplace.

15 Our concerns about the marketplace were
16 further stoked with the July announcement by GE of its
17 intention to enforce software license limitations. As
18 you know when hospitals and group medical practices
19 purchase or lease imaging equipment the return on
20 income commonly anticipates a resale on the secondary
21 market with no additional license cost to the new
22 purchaser. In July, just a few months ago, GE issued

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1 a letter sent to independent brokers of used
2 healthcare equipment stating that unless otherwise
3 explicitly stated by GE Health Care in writing
4 software that is not part of the equipment's base
5 system standard software is non-transferrable and only
6 the original equipment purchaser has a non-exclusive
7 landed license to use such software. In these
8 statements GE has advised of its intention in the not
9 too distant -- in subsequent statements I should say
10 to undertake imaging equipment work in a cloud based
11 platform. It is not entirely clear to us how this may
12 be done and how AIAT responsibilities for the
13 applicable modalities will be observed. This license
14 limitation was not to my knowledge previously enforced
15 and may well come as a surprise to healthcare
16 providers who purchased imaging equipment a few years
17 ago and expect to seek a certain price in the
18 marketplace, a price which now must take into account
19 potential relicensing costs.

20 IAMERS member have noted to me the chilling
21 effect that it already has on their GE equipment
22 sales. We are concerned that this position if

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1 enforced in an already high marketplace will increase
2 substantially licensing costs in the secondary imaging
3 market. We are looking at whether these license
4 restrictions are being enforced only as to some
5 stakeholders but are not being enforced to other
6 stakeholders. We are looking at whether this license
7 limitation enforcement is in the totality of the
8 circumstance an appropriate activity. We have sent a
9 letter to General Electric in July to put our
10 questions and concerns in writing. It is now almost
11 November and we are awaiting a reply.

12 I love movies and in particular enjoy the
13 movie Independence Day. I haven't seen the sequel.
14 In any event there is a scene in which I am reminded
15 in which the U.S. President played adroitly by Bill
16 Pullman has an exchange with the captured alien who is
17 attacking the earth. Pullman asks the alien, what do
18 you want us to do? And the alien as some of you may
19 know ominously says "die". Okay. This is an
20 obviously dramatic reference made just to draw
21 attention because we are concerned that MITA as they
22 are advancing their rulemaking initiative when coupled

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1 with the license limitations may limit healthcare
2 provider options, in effect, the continued existence
3 of independents. We hope that concern is badly
4 misplaced.

5 We believe, however, that the FDA would
6 fairly and appropriately examine the initiative, the
7 evidence behind the initiative and whether compelling
8 evidence exists for a change, not to regulate by
9 anecdote. We will be separately looking at the
10 situation and hope the FTC does as well.

11 We have a hope for a different future; a
12 future of collaboration and cooperation. I, too, was
13 at the Joint Committee meeting of the task force in
14 1997. And that included some who are on the dais
15 today including MITA, including the American College
16 of Clinical Engineering, although I will say that I
17 had understood that that was an interim report and
18 Malcolm Ridgway who is here could probably speak to
19 that because I know he too was involved. In any event
20 it is our hope that the future is one of
21 collaboration, one of training, that training is
22 accessible to the independents.

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1 It has been an honor of appearing here. And
2 we note that when the meeting and the FDA occurred in
3 1997 the joint task force that all who participated,
4 participated in a respectful way at which issues were
5 addressed and consensus development took place.
6 Perhaps it is time to reconstitute a committee of this
7 type.

8 Having spoken to our President Diana Upton
9 earlier today I'm confident that IAMERS would
10 participate if the paramount issues are patient safety
11 and health care costs.

12 Thank you.

13 CAPT. MITCHELL: Thank you, Rob.

14 We are now going to break. According to our
15 computers up here we have 9:59; it will be for 15
16 minutes. And then we will come back.

17 Thank you.

18 BREAK

19 STAKEHOLDER PRESENTERS (continued)

20 CAPT. MITCHELL: So we are going to continue
21 now with our stakeholder presentations. And our next
22 stakeholder is Mark Leahey, the President and CEO of

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1 Medical Device Manufacturers Association, MDMA.

2 And Mark Leahey will be here in just a
3 minute.

4 Thank you Mark.

5 MR. LEAHEY: And the good news is I only
6 plan to speak for about five to seven minutes so we'll
7 still be on time.

8 But thanks very much to FDA and to all of
9 you for coming here today.

10 My name is Mark Leahey. I'm the President
11 and CEO of the Medical Device Manufacturers
12 Association. We are a trade group here based in D.C.,
13 we represent about 300 primarily small to midsize
14 medical technology companies from very sophisticated
15 products to very simple products and we try to be
16 their eyes and ears here in Washington. And the
17 ultimate objective is to ensure that patients have
18 timely access to safe and effective products.

19 Again just hearing a lot of discussion this
20 morning I'm actually encouraged that there seems to be
21 a lot of alignment from all the parties up here about
22 the focus on patient safety. We heard from Dr. Maisel

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1 at the outset some of the key themes here that I think
2 have been reiterated throughout out the panelists.

3 The first being that you need to make sure
4 that there is a quality system and elements of a
5 quality system in place for both the OEMs and third-
6 party servicers. Again, let me say at the outset we
7 have small companies, medium size companies; some of
8 these are OEMs, service providers; some of them use
9 third parties, some of them third-parties to OEMs. So
10 we do represent I think the totality of the ecosystem
11 here. And let me also say that there are absolutely a
12 significant number of high quality service providers
13 and no one is trying to somehow suggest that the OEMs
14 are the only ones who can do this right. That is
15 simply not the case.

16 We also aren't here to suggest that somehow
17 we want to increase costs. And it is interesting a
18 lot of the presentations here about cost, cost, cost
19 and I agree we should keep this within the parameters
20 of what the FDA's jurisdiction is which is safety and
21 efficacy. So I think moving forward we'd all do
22 better in not bringing up issues about market dynamics

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1 because I think we do need to focus on the impact on
2 patient and having validated systems in place, et
3 cetera.

4 And then finally we certainly wouldn't want
5 as it relates to patient safety don't want to do
6 anything that would limit options and servicing in
7 geographic areas. Again, this is an area we want to
8 make sure that patients and the hospitals have access
9 to the service they need to ensure again collectively
10 everybody in this room wants to focus on making sure
11 the patient is best served.

12 So what I'd like to do is try to discuss
13 what I hear are the three things that seem to be
14 consistent thus far in the earlier speakers and I echo
15 hope that we can have a very thoughtful and cordial
16 and meaningful discussion over the next two days here
17 and hopefully end at a place where there are common
18 themes that emerge and then again thus far a few that
19 I've heard is again that high performing third-party
20 servicers whether they be the OEMs or the third
21 parties have quality system in place. It is scalable
22 as Tara said but I think to somehow suggest you are

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1 doing a great job of servicing and you don't have
2 elements of a quality system I think that would be
3 hard pressed to make that case.

4 The second element that I think we've heard
5 all the parties speak about is that you need to have
6 adequate and appropriate training. And again I think
7 everybody here has talked about that that is a key
8 element for both the OEMs and the third parties and
9 again I'm sure there is variation within the OEMs
10 about how they perform and there is variation in the
11 third parties. But adequate training and appropriate
12 training is another core element. And again these are
13 things that I think all the speakers thus far have
14 raised and also the folks at FDA.

15 And then the third element I think is the
16 importance of validated parts. And I am not
17 suggesting that all of the parts have to come from the
18 OEM. We've heard that again if you have systems in
19 place and you can manufacture parts or source parts
20 that are validated that meet the specs and
21 conformance, absolutely they should be able to be used
22 in the marketplace. I don't think anybody up here has

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1 suggested otherwise.

2 So when you look at those three elements
3 here of: elements of a quality system, appropriate
4 training and, validly sourced parts again there is
5 alignment there and I guess the question I have is if
6 we all agree that these are the things that need to be
7 done that are being done; not validating that they are
8 being done seems to be you know that missing element
9 here.

10 And what that solution, and what that
11 validation looks like hopefully we'll discuss in the
12 next two days. I'm sure we have a variety of ideas
13 but to somehow suggest that we all agree these three
14 things are important, but we don't want to you know it
15 is kind of that trust but verify doctrine that I think
16 is important for us to consider as we move forward
17 here. And I hope that as we have this discussion we
18 can find the right size approach here to address these
19 issues to make sure that patients are being best
20 served.

21 And again I think the key here, to close on
22 and I told you I'd be under five minutes so certainly

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1 have about 13 to give back, again no one is
2 suggesting, particularly coming from a group that
3 represents many small manufacturers, that we want to
4 do anything to limit choice, competition, et cetera.
5 But again if this is about the patient having elements
6 of a quality system, adequate training, and a
7 validated source parts and being able to again
8 validate that those systems, those elements are in
9 place I think is critical.

10 So I look forward to the discussion of the
11 next two days and I am confident, maybe I'm the
12 eternal optimist here but we can all find an area of
13 agreement, alignment, and really just solidify the
14 best practices that many in the industry are already
15 doing and make sure that we have consistency across
16 the board.

17 So thanks very much.

18 CAPT. MITCHELL: Thank you, Mark.

19 We will now hear from Tim McGeath, Senior
20 Vice President and General Counsel, TriMedx.

21 MR. McGEATH: I can't promise five to seven
22 minutes but I'll do my best to speed it up.

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1 Thank you and good morning. On behalf of
2 TriMedx I'm please to have the opportunity to address
3 the FDA and interested stakeholders on the important
4 issues on review at this workshop.

5 As was evident by the large volume of
6 comments there are many divergent opinions as to the
7 need for some level of additional regulation or
8 involvement by FDA regarding medical device service.

9 We at TriMedx believe all can agree that the
10 imperatives of patient safety and quality should drive
11 the conversation. And for that reason we applaud the
12 FDA for looking at this issue.

13 My focus today is on service and repair. In
14 short we believe that there is a definite place in the
15 market and a need for third-party service
16 organizations such as TriMedx; that third parties and
17 in-house departments can and do service and repair
18 equipment safely and effectively and that increased
19 collaboration between the parties is essential to
20 providing safe high quality and cost effective patient
21 care.

22 First I want to briefly introduce TriMedx.

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1 TriMedx was formed in 1998 out of the clinical
2 engineering department at Saint Vincent Hospital in
3 Indianapolis under the premise that there was a more
4 efficient way to manage a hospital's diverse and
5 growing inventory of complex medical equipment.
6 TriMedx is one of the country's largest third party
7 provider of healthcare technology management services
8 serving approximately 240 hospitals and 1,800
9 healthcare providers across 34 states.

10 We like to say that TriMedx was created from
11 healthcare to serve the needs of healthcare. TriMedx
12 maintains data for more than 1.4 million pieces of
13 medical equipment and employs nearly 1,500 associates
14 nationwide.

15 Our model is to serve as an extension of an
16 in-house clinical engineering team with a goal of
17 using our size, scale, and concentrated expertise to
18 provide a more robust level of service than many
19 individual hospitals or systems are able to provide on
20 their own.

21 We all know that providing that providing
22 the highest quality patient care is the most important

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1 part of our job. I want to state that point very
2 clearly because all of our comments stem from that
3 critical underlying premise.

4 I would now like to briefly address the
5 benefits of a holistic equipment management approach
6 through an Independent Service Organization or ISO
7 which we believe has relevance to the discussion at
8 hand. While our perspective is that of an ISO
9 certainly TriMedx is not alone in this space. Many of
10 our comments apply equally to other ISOs and in-house
11 departments in many cases.

12 There are compelling reasons for holistic
13 equipment management service and repair program.
14 First it is a very provider centric approach to
15 managing medical devices. As opposed to dealing
16 directly with several vendors of the service of a
17 hospital's diverse inventory, providers are able to
18 rely on a single accountable organization to manage
19 all such issues and seamlessly maintain required
20 service information in one comprehensive database.
21 ISOs can often leverage scale to better meet provider
22 needs.

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1 Second, from accountability perspective
2 persons providing equipment repair and service via an
3 in-house or comprehensive ISO model are part of the
4 hospital's team and far more accountable to
5 physicians, the clinical staff, and perhaps most
6 importantly to patients. Their continuous onsite
7 presence allows them to participate in hospital safety
8 environment care meetings and provide clinicians with
9 the comfort of knowing that a member of their clinical
10 engineering team could jump in on a moment's notice.

11 A third-party's responsiveness; it is simply
12 not feasible for an OEM to have trained technicians in
13 close proximity to every hospital. ISOs and in-house
14 models results in boots on the ground enabling them to
15 regularly round on hospital equipment and positioning
16 them to address issues in real time either on their
17 own or by coordinating service from OEMs or other
18 outside parties when needed.

19 Finally, a fourth factor is cost and
20 competition. A competitive market is critical to keep
21 costs down and further drive the efficiencies
22 necessary in today's healthcare industry. The cost

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1 associated with the exclusive use of an OEM to service
2 equipment can be significantly higher than an in-house
3 or ISO model. A medium size facility can spend three
4 to five million dollars per year in equipment
5 maintenance and repair and a modest size system could
6 easily spend five to ten times that amount. It would
7 not be unusual for 60 to 70% of a hospital or system
8 spend to be on high margin service contracts in non-
9 contracted parts and labor even though the in-house
10 team may perform the bulk of the PM and repair work.

11 Importantly these costs we talk about
12 contribute to the country's already over burdened
13 health care expenditure with healthcare in general
14 making up roughly 17.5% of the GDP. It is clear that
15 an effective equipment management program is key to
16 reducing costs, optimizing services, and ultimately
17 freeing up the financial resources that can be
18 redirected to focus on other areas that are critical
19 delivery and better patient care and serving those in
20 need.

21 As I will mention in order for ISOs and in-
22 house models to be successful there must be increased

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1 collaboration with OEMs including appropriate access
2 to training, parts, supplies and service manuals.

3 Assuming the cited benefits of a third-party
4 service model the question then is whether ISOs and
5 in-house teams can provide quality services in a
6 manner that enhances patient care. A consistent theme
7 in comments by OEMs dealt with safety and the
8 potential for patient harm when service is performed
9 by third parties. However, despite claims to the
10 contrary and beyond isolated examples there are
11 neither data nor trends showing an increase in patient
12 harm when it is serviced by third parties. ISOs and
13 in-house department can equally point to isolated
14 incidents of failed equipment operations which
15 resulted from service by an OEM.

16 Recent studies performed by the ECRI
17 Institute indicated from 2006 to 2015 0.005 percent of
18 reported incidents were related to post-market
19 services compared to 0.2 percent from 1977 to 1998.
20 You've heard that statistic cited by a few other
21 speakers. Failure rate is extremely low suggesting
22 that there is not a systemic problem that the FDA

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1 needs to address. And certainly no problem has been
2 identified that relates to who performed the service.

3 We'll also hear from AAMI about its recent
4 adverse events survey. Its evidence and conclusion
5 also support the notion that there is not a greater
6 risk when service is performed by third parties.

7 Finally other unbiased parties such as the
8 joint commission did not identify evidence of more
9 significant public health or safety concerns in
10 connection with third party servicing of medical
11 devices.

12 Of the issues we do see, many result from
13 user error rather than an error by the servicer of the
14 equipment. These findings may be attributed to the
15 fact that many ISOs have already developed and
16 implemented robust quality programs in response to the
17 existing regulatory and accreditation framework.

18 Organized programs like that of TriMedx have policies
19 and procedures that align with the federal, state, and
20 hospital required regulations and standards pertaining
21 to medical equipment management and record retention
22 to ensure compliance, equipment efficacy, and safety.

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1 Our hospital customers are subject to
2 continued review by government authorities including
3 CMS, state departments of health, as well as
4 accreditation bodies. These regulations and
5 accreditation requirements have shaped policies and
6 programs we maintain. Governing procedures such as
7 inventory management, preventative maintenance
8 scheduling, alert and recall management, incident
9 investigations, and a risk based supplier quality
10 management program. In addition our organization's
11 quality regulatory teams routinely conduct surveys and
12 audits to test the program's quality standards, verify
13 adherence to policies and procedures and ensure our
14 customers are always well prepared and in compliance.

15 We agree with the comments of our competitor
16 Aramark that when servicing activities are conducted
17 by highly trained personnel in accordance with
18 established standards practices and requirements of
19 our regulated healthcare customers such activities are
20 safe and effective way to maintain medical devices.

21 Adding further regulatory oversight or
22 requirements for utilization of OEM services to this

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1 list will not necessarily improve quality of care and
2 patient safety but it will likely increase overall
3 costs.

4 Accordingly, TriMedx firmly believes the
5 existing regulatory and accreditation framework to
6 which in-house departments and third party service
7 providers must comply is sufficient to address patient
8 safety and qualify imperatives.

9 As discussed end users service, repair and
10 maintenance of equipment is currently subject to a
11 multi-layered regulatory and accreditation framework.
12 TriMedx must constantly assure that its services
13 comply with applicable law so that our customers by
14 extension always remain in compliance. We take this
15 obligation very seriously.

16 We appreciate that FDA is charged with
17 regulating the safety and efficacy of many types of
18 equipment used to provide patient care. However, we
19 believe that the current system under the watchful eye
20 of accreditation bodies and CMS is sufficient to
21 ensure that equipment is maintained in the manner that
22 results in safe and high quality patient care.

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1 Further, the lack of empirical evidence to
2 suggest a significant amount of adverse events caused
3 by device services not performed by manufacturers
4 supports the belief that there is no need for
5 additional potentially redundant regulation by FDA.

6 Still if it is determined that additional
7 regulation is needed, such a determination should be
8 made with caution prompted by verifiable data and
9 should not have the unintentional effect of stifling
10 competition and adding further unnecessary cost to
11 health care. At a minimum there should be a focused
12 effort to understand what the potential problem is
13 that needs to be solved before we try to solve it.

14 At TriMedx we enjoy strong collaborative
15 relationships with many OEMs. In our view these OEMs
16 see the forest through the trees and recognized that
17 although we compete at some level working with third
18 parties, indeed all parties in the care continuum
19 leads to efficient service and ensures high quality
20 healthcare delivery. Several OEMs collaborate with
21 TriMedx by offering training courses for our
22 technicians, negotiating discounts on service

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1 contracts and labor, and providing seamless access to
2 parts, service manuals, and materials to name just a
3 few things.

4 However some OEMs serve as blockers and in
5 certain cases we believe engage in anti-competitive
6 practices. Such practices can frustrate the
7 preferences of healthcare providers who ultimately are
8 prevented from implementing a comprehensive in-house
9 program or from purchasing the same services from
10 qualified ISOs. The end result is an increase in the
11 overall cost of health care and a diversion of the
12 health care dollar that could otherwise be allocated
13 to enhancing the patient experience, improving
14 population health, or serving the disadvantaged.

15 These anti-competitive practices take many
16 forms. We have seen OEMs tie agreements for ongoing
17 service and maintenance to the original purchase of
18 equipment, refuse to sell parts unless those parts or
19 repairs are provided by OEM service personnel, refuse
20 to provide service manuals, and even attempt to
21 preclude a purchaser or its agents from performing
22 maintenance or repair on its equipment. Some OEMs go

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1 so far as to pressure purchasers not to use third
2 party service providers under unsubstantiated outcome
3 claims.

4 In the past few months alone we documented
5 communications from at least 18 different OEMs with
6 the following statements or claims. Number one, that
7 only OEMs are qualified to service equipment and that
8 they will not sell service parts but also do not offer
9 training programs of any kind. Two, that they refuse
10 to train any third party employees and this refusal is
11 often tied to a restriction on the purchase of parts.
12 Three, that they refuse to train or work with anyone
13 related to a third party. And four, even blanket
14 communications categorizing all third parties as
15 unqualified and raising the specter of safety concerns
16 without substantiation.

17 This behavior is deceiving and distracting
18 to the goals we have as an industry. The FDA can help
19 break down the walls that certain OEMs have put up.
20 One outcome of this inquiry should be to address OEM
21 practices that restrict healthcare providers or their
22 chosen third party providers from reasonable access to

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1 training, service manuals, parts and diagnostic
2 software.

3 Some stakeholders express concern that third
4 parties may use unqualified personnel to provide
5 maintenance and repair services or do not use properly
6 sourced parts. At TriMedx we budget and spend large
7 sums on training our technical personnel both through
8 internal programs and through OEM or other qualified
9 third party training. Many of our technicians have
10 OEM backgrounds. If OEMs believe a lack of qualified
11 trained third party personnel is a problem then they
12 should agree to provide training to those who will pay
13 a fair price for it and agree to protect the
14 manufacturer's proprietary information. It is neither
15 an answer or accurate to claim that an OEM is the only
16 party qualified to perform service. Thinly veiled
17 excuses intended merely to protect profits or restrict
18 competition can no longer be tolerated.

19 Manufacturers cannot have it both ways. They
20 cannot claim a lack of qualified third party personnel
21 yet specifically deny access to training, parts or
22 even service manuals when a third party is acting as

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1 agent for its hospital customer.

2 In sum we believe the one key outcome of
3 this inquiry should be to address OEM practices that
4 restrict the abilities of third parties and in-house
5 departments from reasonable and affordable access to
6 the training and tools needed to safely and
7 effectively service and repair medical equipment.

8 Collaboration is key and market competition
9 is necessary to drive innovation cost reduction.

10 Another outcome should be consideration of
11 appropriate standards to address legitimate concerns.
12 TriMedx welcomes the opportunity to work with all
13 interested parties to develop appropriate training,
14 quality or certification standards that can serve as
15 industry guidelines.

16 We urge the FDA to assess the above-
17 mentioned issues and clarify the scope of the existing
18 body of applicable law. We believe that to hold the
19 third party service provider accountable to the same
20 standards crafted for manufacturers would ignore how
21 the marketplace has evolved and the complex set of end
22 user regulatory requirements already in play. Simply

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1 adding further regulatory oversight or requirements
2 for utilization of OEM services will not improve
3 patient safety but it will increase costs and may
4 unintentionally reinforce anti-competitive positions a
5 number of OEMs have taken.

6 We recommend clear requirements on access to
7 service and parts and related materials so that
8 healthcare providers can meet the regulatory
9 requirements to which they are subject regardless of
10 whether service is provided by an in-house team or an
11 ISO.

12 Thank you for the opportunity to participate
13 in this important discussion.

14 CAPT. MITCHELL: Thank you, Tim.

15 We will now hear from Katie Ambrogi,
16 Attorney Advisor Office of Policy Planning, U.S.
17 Federal Trade Commission.

18 MS. AMBROGI: Thank you. I have to give a
19 partial disclaimer today that I do not speak for the
20 Commission at large or any individual commissioner.
21 But my comments today do draw heavily on the work of
22 FTC staff and reflect staff's general approach to the

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1 interplay between competition and regulation.

2 I appreciate the opportunity to speak on the
3 FDA's efforts to study the medical device industry and
4 healthcare community that repair medical devices
5 including all the other terms that we've heard here
6 today. I may use some shorthand like presenters
7 before me.

8 The FDA should be commended for its work on
9 evaluating this important issue and for opening up
10 this dialogue to industry stakeholders. At the outset
11 we would urge folks here to consider the significant
12 benefits to competition including price, access, and
13 quality as the agency continues to examine the need
14 for regulatory action and to narrowly tailor any
15 potential future regulations to those addressing well-
16 founded patient safety concerns.

17 Let me take a step back and provide a little
18 context for the FTC's interest here. At the FTC we
19 were founded in part due to a belief that competition
20 is at the core of America's economy and vigorous
21 competition among sellers in an open marketplace gives
22 consumer the benefits of lower prices, higher quality

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1 products and services, and increased innovation.

2 The FTC is charged under the FTC act with
3 preventing unfair methods of competition and unfair or
4 deceptive acts. While the commission is primarily a
5 law enforcement agency it has long recognized that
6 competition may also be affected by the actions of
7 public entities including regulators and legislators.
8 Because of the importance of healthcare and
9 competition to the economy and to consumer welfare
10 competition in healthcare markets has long been a
11 focus of FTC advocacy, research and of course law
12 enforcement.

13 But each federal agency has a role to play
14 when assessing regulation and furthering competition
15 mission through its practices. In fact, recognizing
16 the vital role of competition to U.S. consumers and
17 the economy in April 2016 President Obama issued an
18 Executive Order to increase competition. That order
19 stated that promoting competitive markets must be a
20 shared priority across the federal government. It
21 explained that executive departments and agencies can
22 contribute to that goal by competitive rulemaking and

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1 regulations and by eliminating regulations that create
2 barriers or limit competition without corresponding
3 benefits to the American public.

4 Indeed these things are consistent with
5 long-standing FTC advocacy and outreach. Through
6 written comments in agency to agency relationships we
7 have encouraged legislators, sector regulators and
8 other policy makers to integrate competition
9 principles into decision making processes so that law,
10 rules and policies incorporate competition principles
11 to advance the interest of consumers and citizens.

12 To that end we thank the FDA for hearing our
13 policy perspective today and respectfully suggest that
14 the FDA as it evaluates the need for potential
15 regulations incorporate the role of competition in its
16 analysis and avoid unneeded or unduly burdensome
17 impediments or barriers to competition that
18 importantly would not have countervailing benefits.

19 It may be helpful as these complex issues
20 are considered to evaluate the following framework.
21 First, what is the likely impact of any proposed
22 regulation? Second, what specific and evidence based

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1 justification exist for any regulation that may affect
2 competition? Third, are there any alternatives to
3 broad proposals that would fulfill the important
4 public policy goals including patient health and
5 safety without restricting competition or unduly
6 burdening legitimate business activity?

7 I'll turn to each of these principles in
8 turn. First the FDA may examine the benefit to
9 healthcare providers to having alternative providers
10 for servicing and repair of medical devices.
11 Hospitals today can face significant expenses across
12 the board including the expense of medical device
13 repair. One study published on AdvaMed's website
14 estimates that spending on medical devices and in
15 vitro diagnostics was over \$171 billion or 5.9% of the
16 total national health expenditures in 2013. And the
17 Association for the Advancement of Medical
18 Instrumentation has conservatively estimated the
19 medical device service aftermarket at about \$50
20 billion per year. Third parties, that is either
21 independent service organizations or employed in-house
22 teams, today may serve as viable alternatives that

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1 compete against OEMs to provide servicing, repair, and
2 refurbishment of medical devices and equipment to
3 customers.

4 Now certainly there are legitimate
5 competitive reason why a healthcare provider would
6 choose to purchase both medical devices and repair
7 services from an OEM including potential discounts
8 from receiving products and services together,
9 convenience or any specialized expertise that OEM may
10 have. Indeed the ability to choose to contract with a
11 vertically integrated OEM can be considered a form of
12 competition in and of itself.

13 Nonetheless the public record also has
14 evidence of customers benefiting from in-house or ISO
15 providers competing against OEMs in the form of lower
16 prices, expanded offerings, quality, service, and
17 access. For example one large public healthcare
18 system cited that its biomedical engineering program
19 which gives in-house support for medical technology
20 systems collectively saved the organization \$3 million
21 in Fiscal Year 2015. Another large health provider
22 stated in its public comment on the FDA docket that it

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1 realizes significant savings through the use of a
2 large third-party medical repair company and the
3 savings it derives from the use of that third party
4 entity allows it to invest in improving its care
5 delivery model.

6 Yet another mid-sized healthcare systems
7 public comment likewise explained that unnecessarily
8 mandating medical devices and equipment to be repaired
9 or serviced by an OEM or third party outside of the
10 organization that owns the equipment does not best
11 serve patients, adds to the cost of care, and
12 increases unnecessary resources. That evidence as
13 well as other comments in the record suggests that
14 some healthcare providers are benefiting from
15 meaningful competition from in-house service teams and
16 ISOs and that high quality third party repair groups
17 which employ knowledgeable and trained professionals
18 can offer providers significant savings and expand
19 access to these services.

20 Second on the issue of specific
21 justifications for any future potential regulation
22 folks may wish to continue to closely analyze the

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1 available empirical evidence to determine the extent
2 to which health and safety problems are verifiable and
3 connected to OEM or non-OEM repair.

4 The FDA announced that it is evaluating the
5 issue of medical device service and repair in part
6 because some in the industry have expressed concerns
7 about quality safety and continued effectiveness of
8 medical devices subject to service by both OEMs and
9 third-parties. And indeed the FDA's mission is to be
10 responsible for public health by assuring the safety,
11 efficacy, and security of medical devices as well as
12 drugs or other products.

13 Certainly patient health and safety is of
14 critical importance. The FTC frequently grapples with
15 health and safety concerns raised in the context of
16 our anti-trust work and we often turn to independent
17 experts, clinical and economic, to ensure that we are
18 getting the analysis right.

19 Evidence of specific safety issues as well
20 as identifying the root cause of such issues will best
21 guide policy decisions. To that end the FDA correctly
22 put the question to stakeholders; what evidence exists

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1 regarding actual problems with the safety and/or
2 performance of devices? We take note of the comments
3 in the public record and the statements here today
4 that data on faulty or flawed repairs are difficult to
5 collect and so may be unavailable for stakeholders and
6 the FDA to study. And certainly several responders to
7 the public record submitted comments presenting
8 examples of certain medical devices that do not appear
9 to have been serviced correctly leading to concern on
10 the part of some stakeholders.

11 At the same time the public record also has
12 comments by organizations on whether medical device
13 repair has resulted in safety risks to patients. For
14 example the ECII Institute which monitors medical
15 device problems and hazards and which has been talked
16 about by others this morning conducted database
17 searches spanning the last ten years and based on
18 those searches does not believe that a safety problem
19 exists for servicing, maintenance and repair of
20 medical devices by OEMs or third party organizations.
21 In addition the Joint Commission having conducted a
22 large scale hospital survey including such issues in

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1 2012 said that it has no knowledge of any
2 statistically significant level of safety problems
3 resulting from the activities of any kind of
4 maintenance or service provider.

5 So we would urge that to the extent that
6 such information is available that stakeholders
7 continue to seek out and thoroughly study independent
8 sources of data and information to determine the
9 existence and degree of legitimate safety concerns
10 tied to servicing and repair of such devices.

11 Third if the FDA ultimately determines that
12 regulation is needed here we would encourage any
13 regulation to be narrowly tailored to remedy the
14 evidence based source of patient harm. Such an effort
15 would examine exactly where and how the compromised
16 conduct occurs and work with stakeholders to construct
17 solutions designed to address that specific conduct.
18 For example in the public record some OEMs expressed
19 concern that they did not know whether an ISO had
20 worked on one of its devices and so did not know what
21 was done or when to change it from its original state.
22 If such behavior has indeed led to health and safety

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1 risks one suggestion also made in the public comments
2 was that OEM devices repaired by a third party could
3 be labeled to indicate that the repair had been
4 performed.

5 Other suggestions offered that ISOs could be
6 made to notify customers that they are not an OEM
7 authorized service provider and they could be
8 prevented from using registered OEM trademarks that
9 may confuse or mislead.

10 Such provisions which focus on improving
11 communication and potentially giving more information
12 to the customer would be less restrictive alternatives
13 to broad prohibitions on ISOs or in-house groups
14 competing in the after-market. And indeed the FTC
15 through our consumer protection arm has long worked to
16 ensure that any advertisement in any industry are
17 truthful and not misleading.

18 It is also worth considering as others have
19 mentioned whether there is existing governance in this
20 field and whether additional regulation would be
21 constructive. To the extent that organizations are
22 already regulated or overseen in certain aspects of

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1 medical device repair and servicing one may consider
2 whether additional regulation would add anything
3 additional to the mix.

4 The goal of narrowly tailoring regulations
5 is first to cure any legitimate harm while preserving
6 the benefits of competition.

7 In conclusion we once again appreciate the
8 opportunity to be heard on this issue and commend the
9 FDA for bringing together such a wide variety of
10 stakeholders. We welcome future participation and
11 discussion and other organizations as this continues.

12 Thank you.

13 CAPT. MITCHELL: Thank you, Katie.

14 We will now hear from Mary Logan, President
15 and CEO of the Association for the Advancement of
16 Medical Instrumentation, AAMI.

17 MS. LOGAN: Thank you. This is my last
18 public appearance today and tomorrow as AAMI's
19 President and CEO because I'm retiring at the end of
20 the year. So I'm going to say something at the end of
21 my remarks but I want to start my remarks by doing
22 something really fun.

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1 I went to my first baseball game,
2 professional baseball game when I was nine at Wrigley
3 Field so that is what I am going to say, "GO CUBS".

4 [Laughter]

5 I think most people here know who AAMI is
6 but I wanted to put a slide in the record for anyone
7 who might not. AAMI is an association, but we are not
8 a trade association, we really could be a charitable
9 organization, a 501(c) (3) because we don't do
10 lobbying or advocacy.

11 What makes people want to participate in
12 AAMI is that we are all about the technology. Our
13 focus is on the technology itself and the whole
14 community of people who work with healthcare
15 technology. Our members are all tech oriented. So
16 sometimes nurses, sterile processing professionals,
17 physicians, other clinicians, healthcare technology
18 management professionals, technology folks who are in
19 the C-suite in healthcare delivery, medical device
20 manufacturers, distributors, parts companies, ISOs,
21 refurbishers, third party repair. We have the gamut.
22 That makes this issue really interesting for us, also

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1 very complex.

2 We normally don't submit comments to the
3 Federal Register for the many, many opportunities that
4 we could because we normally don't have anything to
5 say. We might file a letter reminding people to
6 remember person safety is really paramount.

7 In this instance we wrote a very lengthy
8 comment because we thought that we had a unique
9 perspective of speaking to the whole industry, the
10 whole service industry rather than to any one of its
11 component parts. So it is a lengthy document.

12 The survey that was mentioned earlier is
13 attached to that. AAMI was asked by the Joint
14 Commission to perform that survey unrelated to this
15 particular docket item.

16 So our focus, our mission is advancing
17 safety in healthcare technology. So it is all about
18 the safety and performance of the technology itself.

19 We are primarily known for standards
20 development and the next slide I'm going to show will
21 explain why we are primarily known for that. We also
22 do a lot of education, training. Our foundation has a

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1 lot of focus on patient safety initiatives and we
2 address other technology oriented issues like
3 wireless, cyber security. We are a convener and I
4 think we have become perhaps as well known as a
5 convener as a standards developer because to quote Pat
6 Baird from Philips we are known as Switzerland because
7 we don't advocate for anyone position or another.
8 We're a great place for people to come together to
9 develop consensus and to try to find common ground.

10 We also do a lot of publications and we have
11 staff here. Our publication staff are here today, we
12 are always looking for ideas for new issues to write
13 about. So if you have suggestions for that, please
14 let us know.

15 And personnel certifications; a lot of you
16 might not know that we are ANSI accredited as a
17 personnel certification organization for our BMet
18 certification. So we have a certification program
19 that verifies the credentials of the biomedical
20 equipment technicians.

21 These are select examples of AAMI standards
22 in this space. And tomorrow at the end of the day I'm

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1 on a panel with five minutes to talk about standards.
2 So I'll do a little bit more about those but I wanted
3 everybody to see the overall scope of our standards
4 development program. And we have over 10,000
5 volunteers who help serve as the subject experts and
6 help write the standards.

7 There are a number of standards that apply
8 to service. So when I speak of service, repair, and
9 refurbishment I am using all of those definitions just
10 referring to the service industry in a very broad way.
11 As a result of this docket we have a brand new
12 committee that will have its first meeting in December
13 to develop definitions. It was really clear in
14 looking at the comments submitted and in the questions
15 that the FDA asked that there is a need for
16 standardized definitions. So we have approval from
17 ANSI to start a committee to develop the definitions.
18 So we hope that many of you will want to join and
19 participate in that activity.

20 We also have a new committee that is going
21 to be looking at a standard for acquisition of
22 technology. So I think you are going to see more and

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1 more standards being developed on the service side as
2 opposed to on the manufacturing side. Very strong and
3 many standards on the manufacturing side and the
4 industry side; not as many on the service side and
5 there is a great need for more which I'll say a little
6 bit more about tomorrow.

7 Interestingly electrical safety,
8 sterilization, industrial sterilization, quality
9 systems has been mentioned earlier, risk management,
10 cyber security, network risk management, and software
11 are all areas where AAMI standards could apply to
12 service.

13 This is the cover of the most recent issue
14 of our peer review publication BINT. And it is about
15 this issue. So it is a very jazzy cover and Sean
16 stand up for just a minute. Sean Loughlin is VP of
17 communication at AAMI, if you don't have a copy of
18 this, if you are not an AAMI member or you missed it,
19 Sean has copies, you can see him at lunch and he'll be
20 happy to give you a copy.

21 The common thread of every single person who
22 participates in AAMI on this issue and every other is

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1 I care about patient safety; that is what makes the
2 staff at AAMI inspired to come to work every day
3 because that is really what it is all about. That is
4 the common ground.

5 There is a lot of other common ground though
6 with this issue in spite of the cover which is also
7 very true. There is common ground that folks who work
8 on technology should be trained properly; that onsite
9 support has great value; that people should have the
10 right credentials and qualifications before they work
11 on equipment no matter who they work for; that
12 sourcing of parts is very important and access to
13 validated parts is real important; access to
14 information; access to the information that people
15 need to be able to assess what is going on with a
16 device, to be able to repair it, to be able to
17 troubleshoot it, and to be able to know if there is
18 actually something wrong with a device for purposes of
19 a full life cycle improving the design, updating a
20 design.

21 Whether or not the folks in this room and
22 folks who are listening out in the field would agree

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1 with this you are all inextricably linked of that life
2 cycle of the device itself. And the feedback of good
3 information among all of you is essential to patient
4 safety.

5 Process validation, I think everyone would
6 agree process validation is something that where there
7 is common ground.

8 There are differences of opinion about
9 whether there is a problem, whether there is evidence,
10 what the extent of the problem is, the cause of it,
11 and interestingly there is a pretty significant
12 difference of opinion about whether or not there
13 should be additional regulation. Normally AAMI
14 members share a view that additional regulation is not
15 a good thing. Folks like standards as an alternative
16 to regulation across the spectrum.

17 On this issue there is a divide and I think
18 this slide, it is going to be a little hard for you to
19 read the details but I think you can get the sense of
20 it. This slide says it all to me. So this is from a
21 Systems Engineering textbook from when Wil Vargas on
22 our staff went to engineering school and the title is

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1 "Dream Airplanes" and its photos of the drawings are
2 of dream airplanes from the prospective of the
3 engineer and what group the engineer worked in. So
4 you have the fuselage group, the controls group, the
5 hydraulics group, the service group, the wing group,
6 et cetera, et cetera. And the airplane looks very
7 different depending on what group the engineer works
8 in. I'm a big proponent of systems engineering and
9 systems thinking because unless you have everyone in
10 their full life cycle together in the room solving a
11 problem you are going to create an airplane that looks
12 like this.

13 And that sometimes happens with regulations
14 as well. Sometimes when the FDA doesn't get the
15 perspective of all the stakeholders what they end up
16 with as a regulation might look like it came from the
17 loft group or the stress group or the power plant
18 group instead of an airplane that everyone has
19 imagined together.

20 So AAMI's primary role and the role that I
21 envision, easy for me to say because I'm a short timer
22 now, is building from the common ground. Since I have

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1 been at AAMI and before I came to AAMI there was a
2 consistent drum beat from healthcare delivery
3 organizations on the service side of the business that
4 AAMI needed to do something to help with the problem
5 of industry and service organizations not seeing eye-
6 to-eye on the supportability issues around medical
7 devices.

8 So we were crazy enough to have a forum last
9 year on supportability. And this artwork you can find
10 on our website or if you see Patrick, where are you,
11 Patrick Bernat from my staff was the host of that
12 event if you want to learn more about it. We had in
13 an artist map the discussions and map the common
14 ground. This particular slide shows the "we believe
15 that" statements. This one shows the building from
16 the common ground. It was an event that was attended
17 by both industry and folks from healthcare delivery
18 all again with that common goal, that common interest
19 of advancing the safety of technology.

20 As a result we have now a supportability
21 task force and that supportability task force has two
22 immediate deliverables. One to define and fill the

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1 gaps in terminology. The language used by service
2 organizations and manufacturers is very different. So
3 one of the things they are working on is filling that
4 gap to have the common understanding of terms. Their
5 other deliverable is to have a template for service
6 level agreements which should help industry and
7 healthcare delivery organizations.

8 I mentioned we have two new standards
9 committees that are starting up, they are both meeting
10 in December -- two new standards that will be
11 developed by our EQ committee. One to work on the
12 definitions that are part of this docket. So thank
13 you FDA for identifying that there was a need for
14 definitions. We think our committee can define the
15 terms better than the regulators can. Sorry FDA.
16 We'd like to see that done in a standard. Another
17 committee on acquisitions.

18 We also think there is a lot more that AAMI
19 can do. The cover story from the October issue of
20 BINT really laid out all the issues. We need more
21 articles like that to identify where other areas where
22 we can find common ground as well as annual conference

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1 sessions, webinars and whatever else any of you from
2 our community might suggest that we can do, please let
3 us know.

4 If you are interested in being a part of the
5 standards work, Amanda Benedict, her email address is
6 on this slide, would be the person to contact. She
7 needs you, she welcomes you.

8 The supportability task force, Patrick is
9 here, you can speak with him at a break or send him an
10 email as well.

11 So I want to just take one moment of
12 personal privilege since this is my last public
13 meeting. I'm retiring at the end of the year. And
14 the search committee that has been working hard all
15 year has named my successor, Rob Jensen who is a
16 senior leader at MITRE, MITRE's health IT practice --
17 health IT business will be joining AAMI on November 14
18 and I hope that you all will be as wonderfully
19 supportive of Rob's success as you have been of mine.
20 It has been such a privilege to get to know all of
21 you, to serve you and to be in this space of convening
22 people to do their best work. I am going to miss

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1 that.

2 Thank you.

3 CAPT. MITCHELL: Thank you, Mary.

4 Just hold on for a few minutes. In just a
5 few minutes we are going to go ahead and break.

6 Let me just first say thank you to all the
7 panelists. It is clear from this first session that
8 it is really, really helpful to have everyone together
9 talking to understand the depth and breadth and
10 complexity of this issue.

11 Certainly we have differing opinions but as
12 many people have already identified there are some
13 commonalities. I just want to highlight a couple.

14 One is the value of the ISOs, the importance
15 of collaboration and cooperation. And finally that
16 each and every patient encounter should be both
17 successful and safe.

18 And lastly but not least is that decision
19 making should be based on data.

20 So with that I want to give you some
21 instructions for lunch and then because we are
22 convening early I'm going to ask that you all come

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1 back at 12:30 instead of a 12:00 to 1:00 lunch. So I
2 hope that is going to work for everyone.

3 With regard to lunch you've all pre-ordered
4 in different ways. Some of you have paid and some of
5 you have not. When you go outside you will find three
6 lines. If you have exact change, \$11.00 you are in
7 one line. If you are going to use a charge card you
8 are in another line. And if you don't have exact
9 change but you do have cash you are in another line.
10 And then if you've paid already, I didn't get told
11 about that one but I assume that there is another
12 line.

13 [Laughter]

14 Thank you very much for your attendance this
15 morning and we'll see you at 12:30.

16 LUNCH

17 CAPT. BOYD: So welcome back to our
18 workshop. My name is Sean Boyd. I'm the Deputy
19 Director for Regulatory Affairs in CRH's Office of
20 Compliance. And I'm just going to lay out an
21 introduction of what this afternoon's program holds.

22 But before we get to that we are going to

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1 continue the discussion of lunch. Tomorrow to avoid
2 some of the issues that we had today the vendor is
3 going to be available during the break this afternoon
4 to take preorders and payment for lunch tomorrow. We
5 anticipate the break is going to be between 2:00 and
6 2:30 based on adjusting our schedule so if you would
7 like to preorder today you can go and do that this
8 afternoon. They'll also arrive earlier tomorrow
9 morning by 7:00 a.m. so that you'll have an
10 opportunity to do that early tomorrow morning.

11 Moving on with our program; this afternoon
12 we have a panel on the benefits and risks associated
13 with refurbishing, rebuilding, remarketing,
14 remanufacturing, and servicing activities. The panel
15 session will have presentations from each of the three
16 stakeholder groups represented that include
17 manufacturers, service providers and hospital end
18 users and engineers. Each group is going to present
19 their viewpoints regarding the benefits and risk
20 surrounding these activities with medical devices.

21 And following their presentations the floor
22 will be open to questions and you may address the

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1 panel as a whole or individual speakers on the panel.

2 Following the panel again we are going to
3 have a short break and continue with presentations by
4 workshop participants. Due to the overwhelming
5 interest in this workshop and in speaking during the
6 event we've pre-scheduled several speakers for the
7 session and with time permitting the floor may open to
8 the audience as well. Each presenter that has been
9 allocated time will have five minutes this afternoon
10 to make their remarks.

11 So thank you again for being here.

12 And with that I'm going to allow Pam Scott
13 to moderate this session.

14 MS. SCOTT: Good afternoon. Again thank you
15 all for attending this important workshop. So we are
16 going to get right into our next session, Panel Number
17 1. And at this time what I'm going to do is I'm going
18 to introduce our panelists. And I hope that I
19 pronounce all my names correctly. If I don't please
20 feel free to correct me.

21 And I'm going to give just a bit of an
22 overview, just a quick snapshot of the bio of the

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1 wonderful expertise and knowledge that we have as a
2 part of our first panel this afternoon.

3 We have Mr. Pat Baird. He is the head of
4 Global Software Standards with Philips. Mr. Baird has
5 extensive background in risk management and chaired
6 international conferences on medical device risk
7 management in 2011 and 2012. He has chaired and
8 served as a member on numerous technical committees
9 focused on medical device safety. He also serves as
10 an adjunct instructor for topics such as insurance
11 cases, risk management, human factors, and software
12 validations.

13 Next on our panel we have Mr. Mark Leahey.
14 He is the President and CEO for the Medical Device
15 Manufacturers Association. Again this is the national
16 trade association that represents medical technology
17 companies. His current responsibilities include
18 advocating on behalf of the entrepreneurial sector of
19 the medical device industry to Congress as well as
20 federal and state agencies. Mr. Leahey has a
21 background and experience in both law and business.

22 We have Ms. Kanchana Iyer; did I get it

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1 right? Almost, close. Kanchana I believe that is
2 better Iyer. She is a Senior Regulatory Affair
3 Specialist at PENTAX Medical and Endoscopic Imaging
4 Company. She is a biomedical engineer with background
5 in biomaterials, computational modeling and tissue
6 engineering. She formerly served at FDA as a lead
7 reviewer within our Office of Device Evaluation as
8 well as a Regulatory Communications Project Manager in
9 the Office of Communication and Education.

10 We also have on our panel Mr. Hans Beinke.
11 He is the Vice President of U.S. Quality and
12 Technology with Siemens Health Care. He has been in
13 the pharmaceutical and medical device industries for
14 nearly 40 years. He has extensive background in
15 pharmaceutical development, clinical trials, medical
16 device, environmental health and safety, quality,
17 regulatory and clinical affairs.

18 We also have Mr. Scot Mackeil. He is a
19 Senior Anesthesia Biomed at the Massachusetts General
20 Hospital in Boston, Massachusetts. Mr. Mackeil
21 obtained his CBET certification in 1994 and is
22 currently responsible for providing technical support

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1 to staff in the Departments of Anesthesia, Surgery and
2 Perioperative medicine in direct support of patient
3 care activities. He also performs preventative
4 maintenance and repair on medical equipment and
5 systems throughout the OR and anesthetizing locations
6 around the hospital campus.

7 We have Mr. Mark Bruley who is a Biomedical
8 Engineer and Vice President for Accident and Forensic
9 Investigations at ECRI Institute. Since 1982 he has
10 been responsible for ECRI's accident and forensic
11 investigation program. He has published extensively
12 and lectured on medical device accident and
13 investigation, health care and medical device problem
14 reporting programs and a wide variety of patient
15 safety topics.

16 We also have on our panel this afternoon Dr.
17 Robin Hemphill. She serves as the acting Assistant
18 Deputy Under Secretary for Health for Quality, Safety
19 & Value at the VA National Center for Patient Safety.
20 Dr. Hemphill has extensive experience in emergency
21 medicine, disaster preparedness and healthcare
22 quality. She currently focuses her efforts on

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1 aligning the VA's quality, safety and value offices as
2 well as developing a strategic plan to build process
3 improvement on top of a foundation of patient safety.

4 We have Ms. Wanda Legate. She is a partner
5 and serves as the Vice President of Sales and
6 Marketing at Tri Imaging Solutions. She has over 20
7 years of experience in the diagnostic imaging industry
8 both with an OEM as well as independent providers.
9 Throughout her career Ms. Legate has held various
10 management positions with a focus on customer service,
11 sales and creating a market presence.

12 We have Mr. David Anbari. He is Vice
13 President and General Manager for National Sales and
14 Operations at Mobile Instrument Service and Repair.
15 Mr. Anbari leads a team of field service and repair
16 engineers and technicians in the delivery of services
17 to healthcare facilities nationwide. He blends a
18 respect for the technical elements of the central
19 sterile environment as well as the materials
20 management, biomed and operating room environments
21 with over 24 years of business focus operations
22 management expertise.

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1 And we have Mr. Rob Moorey who serves as
2 Division Vice President for TriMedx, LLC, a service
3 organization in healthcare. He leads the East Coast
4 or the East Central Division and he has over 20 years
5 of experience leading operations for industry,
6 spearheading many initiatives that have delivered
7 sustainable programs and serving on international
8 medical mission efforts and consulting to Catholic
9 Health Care in Haiti on the structure of their
10 national service organization.

11 This concludes the introduction of all of
12 our panel members. And at this time I am going to
13 hand it over to Mr. Baird to begin our discussion with
14 the first presentation.

15 PANEL 1 PANELISTS:

16 BENEFITS AND RISKS ASSOCIATED WITH REFURBISHING,
17 RECONDITIONING, REBUILDING, REMARKETING,
18 REMANUFACTURING, AND SERVICING ACTIVITIES

19 MR. BAIRD: Great. Thank you.

20 Okay. So first of all I'd like to just sort
21 of thank the other members of this panel for helping
22 me put together this presentation to begin with. We

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1 had a couple of iterations clarifying some things.

2 And then I also wanted to mention that my

3 wife is a technical writer and occasionally I will

4 pick not quite the right word and she'll correct me

5 immediately and I know that while some of these

6 definitions for manufacturing, refurbishment, et

7 cetera, they are not finalized. I'm sure sometime

8 during my presentation I'm going to use a little

9 different word than what it needs to be in the end.

10 And so I'm trying to get across to you the intent of

11 what we're trying to do even if sometimes I pick just

12 the wrong word by a little bit.

13 And really we are focusing on the big

14 picture risks. Of course there is going to be some

15 difference in risk say from a servicing activity than

16 a remanufacturing, remarketing activity. The main

17 focus is on some of the key drivers beneath that.

18 So I always like to start with some take

19 aways, just to say this is what I'm going to be

20 talking about. To me this is a patient safety issue.

21 My background is in risk management and patient

22 safety. My background is in making customers as happy

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1 as possible in a safe and effective way. This is a
2 patient safety issue. That is why I'm participating
3 here.

4 Another thing that has been touched on
5 briefly but I want to go a little bit deeper is what
6 I'm calling the invisibility factor. I should have
7 actually called it invisibility factors because there
8 are many ways in which things aren't obvious and that
9 is driving certain behaviors and that is driving
10 certain conclusions. So I'll talk about that in a
11 little bit.

12 I also wanted to mention that when I walked
13 in the doors today I thought that I was at a AAMI
14 conference because Mary Logan was talking in the
15 morning and I recognized about a half dozen HTM
16 (health technology management) professionals from
17 this. So it is like, oh, yes, these are people that I
18 already know and I want to be clear on this is that
19 lots of service providers are doing the right things
20 and have good controls in place. There are other
21 service providers that don't appear to have some of
22 these capabilities. And as a manufacturer I know that

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1 the service activities that are done by any
2 manufacturer aren't 100% perfect all of the time.
3 Completely taken and understand that. One think that
4 I like on the manufacturing side though is that we
5 have non-conformances and CAPAs and things to detect
6 problems as quickly as we can and act on them and put
7 the things in place. This is one thing that I
8 actually like about quality management systems is that
9 continuous improvement and including those things.

10 Also wanted to mention as part of the take
11 aways from this is the documentation and the reporting
12 of things back to the OEMs. I'll go a little deeper
13 on another slide about this. But this is one of those
14 things where having a holistic picture of the health
15 of individual product and how well is it performing is
16 being skewed, is being clouded by not having all of
17 the information that we could have. That of course
18 could lead to more safety and performance issues.

19 So I do want to talk about the benefits of
20 sort of good servicing practices. Obviously devices
21 will last longer, right, if they are serviced and
22 maintained appropriately. Not only do they last

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1 longer but there is a longer mean time between
2 failures, right, so it doesn't have to go back in the
3 shop so often.

4 Competition; there was some discussion about
5 competition. When I talk to other manufacturers we're
6 all for competition on these things. That is how our
7 economy works. I was talking to a small company a few
8 months ago and they had brought up the broader
9 geographic coverage and this was a small manufacturer
10 who is very happy to be a small manufacturer. And
11 they had a good product, they wanted to take and
12 expand into other regions but they don't have the
13 infrastructure to set up the service depots; they
14 don't have those things. So as we are having these
15 discussions they are like make it clear I am relying
16 on ISOs to support my business model. This allows me
17 to go into new areas that I wouldn't be able to get to
18 otherwise. I love this stuff.

19 And then also back to that we have a cloudy
20 picture of what's going on but the OEMs have
21 responsibility to take action when we see an uptick in
22 certain kinds of complaints, certain kinds of

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1 failures, et cetera. And when we have all of that
2 information back in our hands we get a much fuller
3 picture of the health of the device and where we need
4 to work on things.

5 So again this is a patient safety issue. I
6 view the world as patient safety. Regulations exist
7 because if you have untrained personnel, you have
8 uncalibrated test equipment, you are buying parts from
9 unapproved supplier; there is a risk there. And to me
10 that risk is the same no matter who the person is
11 doing this. And so if regulation is important for
12 safe and effective products shouldn't it apply to
13 everyone that is doing those types of activities.

14 So going just a little bit deeper into risk,
15 again this is about patient safety, it is about
16 product performance. If the device isn't performing
17 as it should, well then healthcare professionals can't
18 do their jobs. The device isn't meeting all of its
19 specs and the patient is the person in the crosshairs
20 when it comes to safe and effective matters.

21 I've been on some of my own devices in my
22 past life. I've been on some competitor's devices.

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1 And I shouldn't have to worry about whether or not
2 there is an equivalent level of safety depending on
3 who it is that last touched that device.

4 Additionally talking about sort of that
5 documentation on the manufacturing side we keep track
6 of all the changes made to an individual device. We
7 know the service history for all of these things. And
8 if some things happen that we don't know about next
9 time it comes back to our shop we might end up doing
10 the wrong thing. If parts get swapped out back and
11 forth between different devices there is a certain
12 traceability. On many designs it doesn't matter. On
13 some designs, on some situations it really matters
14 that this subassembly only works with this version of
15 that subassembly.

16 Additionally if we can't trace those
17 products, if we do have a field issue, if we do need
18 to take and communicate to all of our customers some
19 people are going to get missed because we have
20 incomplete records about some of those devices, about
21 where those devices have been.

22 Some of the contributing factors to these

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1 things really comes down to the complexity of these
2 medical devices. Things are a lot more complex than
3 they used to be. And so there is that extra level of
4 training, that extra level of understanding that you
5 need to do. Some of this complexity comes in just the
6 components themselves. Sometimes the components are
7 very unique or made of special materials. You can't
8 just reverse engineer something. I have used the
9 example in the past of there is a part that looks
10 relatively innocuous but there are some features on it
11 that as a manufacturer I control to within a couple of
12 thousandths of an inch. If someone else has reverse
13 engineered this part think that they've made a
14 comparable part but don't know one particular
15 dimension is really, really critical well then they
16 are going to miss some of the safety features; they're
17 going to miss some of the aspect of that design.

18 Also some specialized knowledge depending on
19 the type of the device. Obviously equipment that
20 emits radiation, things with big magnets, there is
21 extra physics involved with some of these things.
22 Even for something as straight forward as an infusion

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1 pump, there are some interface things between how the
2 sensors interact with the tubing and that is not
3 necessarily common knowledge. You might think you
4 know how this thing works but there is actually
5 another level of understanding that needs to happen.

6 And I also wanted to mention, highlight this
7 last point particularly with the rise of hospital
8 acquired infections cleaning agents, disinfecting
9 agents have changed over time. The type of material
10 selection that goes into some of these devices, some
11 of these components can be really, really important.
12 And just because the thing is the right shape and has
13 the right couple thousandths of an inch as I was
14 mentioning before and fits right in doesn't mean that
15 it is actually going to hold up in this clinical
16 environment with some of the chemicals that are out
17 there.

18 I happen to be extremely sensitive to this
19 topic of HAIs [Healthcare Associated Infections], I'm
20 just admitting my bias, because I lost my mother to
21 one. And so I'm trying to be really, really careful
22 when it comes to how do we make things as robust as we

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1 can for the current healthcare environment. And if
2 you don't know those material factors that is going to
3 be a problem.

4 So I talked about invisibility before and we
5 did have some discussion, well, there was an abundance
6 of discussion earlier through multiple speakers on
7 this issue doesn't really show up in the complaints,
8 this issues doesn't show up in the MAUDE database.
9 And so there is some discussion about whether or not
10 things are being reported, there is underreported, et
11 cetera. I know from my life of two incidences that
12 were filed as MDRs happened I believe within 12 months
13 of each other where medical intervention was required
14 to prevent catastrophic outcomes to two different
15 patients. So I think that we should take a really
16 hard look at whatever data sources that we are using
17 and making sure that we do know the extent of the
18 problem.

19 I also think that there is a challenge on
20 how do I tag this inside of MDRs so that someone that
21 is trying to do data mining later knows what to look
22 for and the key word that my department is using is

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1 that the same or different than the key word that my
2 competitor is using. And so maybe something that we
3 can take and talk about is is there a common taxonomy
4 that we should take and use to identify some of these
5 items so that we can truly see how big of an issue it
6 is.

7 Another part of the invisibility it is not
8 just about the underreporting as it were but it is
9 also when performing some of these repairs and
10 performance of these process steps if -- you can take
11 a look at the processes say I don't see the value in
12 this, I'm going to save time, I'm going to skip this
13 step. Sometimes I completely understand you don't
14 understand why you need to do something so I'm under
15 time pressure, let me skip that thing. Let me go buy
16 a cheaper part from some other supplier because it
17 looks the same, I measured it, they are the same
18 dimensions. And there are subtle things in there that
19 aren't visible to the person performing the service
20 that actually end up being rather significant.

21 There are changes to the design over time.
22 And there are some configuration management issues

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1 which OEMs have to take and deal with those headaches
2 all of the time but that's part of our job is managing
3 those configurations and knowing that this part really
4 is just compatible with this version of that other
5 part.

6 And then finally for the invisibility
7 factors sometimes when there is an error in servicing
8 and it's the OEMs or ISOs or whomever the error might
9 not get detected right away. It might be not until
10 months later that the thing manifests itself. My
11 examples about the disinfecting agents; it takes time
12 for those chemical to take and attack the plastics and
13 make the plastic brittle and then suddenly you see a
14 spike in the number of complaints related to broken
15 things. It could take a while for the effects to
16 accumulate or it could be that this one particular
17 feature is put in for a certain situation. That is
18 not a situation you run into everyday in the hospital.
19 But it is part of the bounds of how the device
20 performs. I'm thinking hot days, humid days, heat and
21 transport kind of uses where the device just sitting
22 there might perform perfectly but because of some of

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1 these configurations issues, because of some of these
2 other errors, you don't really notice that something
3 bad has happened until you are in that situation.

4 And then it was mentioned before I wanted to
5 mention again is that Image RA actually has a nice
6 guidance document on running the HTM departments. I
7 did a quick check last night sort of bouncing what I
8 would think would be in the QSRs that are appropriate
9 for servicing of devices against what this guidance
10 document says. And about 80% of what I think the QSRS
11 for good servicing would be are including in this
12 already. And so I thought it was very interesting
13 that across the pond they sort of have these things in
14 place.

15 And thank you very much.

16 MS. SCOTT: I failed to mention that of our
17 panelists Pat actually represented the OEMs.

18 Now I believe for the hospital end users and
19 engineers I believe some of you were going to split
20 that up in terms of the presentation. So do we want
21 to start with, so we have 15 minutes for that whole
22 segment so you all probably would have about five

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1 minutes each. So Mark do you want to start -- note
2 Mark Bruley, Mark Bruley do you want to start out that
3 segment or we can have Scot Mackeil or Robin or Dr.
4 Hemphill? Well, let's start with Dr. Hemphill. It
5 seems like you may be ready.

6 DR. HEMPHILL: All right. You can see we
7 really organized on this one.

8 Just a couple of thoughts and this is from
9 the section for the hospital end user and engineers.
10 So as you can imagine from a VA perspective I would
11 try and speak to really sort of a high level of issue
12 and how we try to think about these and very much how
13 we're trying to learn as new technologies come in. So
14 you know VA is a large integrated healthcare system
15 and we are trying to serve upwards of nine million
16 lives in that system. So it is a broad portfolio in
17 technology that is being brought into the system and a
18 very skilled set of health technology managers,
19 biomedical engineers that we try to train effectively,
20 maintain their skill sets and then help them do their
21 jobs. And when we think about technologies we view
22 them very much as a continuum of activity. So we are

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1 really trying to think all the way from how is the
2 manufacturing thinking, designing, testing their own
3 systems. So it goes from that design and build into
4 use life cycle management and ultimately you might say
5 age out, so to retirement.

6 Now when we think about retirement we think
7 of them in terms of old stuff that certainly might be
8 perfectly appropriate for people to reuse, refurbish.
9 And then things that we'd be concerned about and we
10 always wonder if something is a really design flaw, a
11 bad design flaw how do we ensure that that doesn't
12 really ever get into a reusable market. And again we
13 feel sometimes there is not always good eyes on that
14 to really track those through time and effort to say
15 this is something we wouldn't want to use. And we see
16 examples of this so I often bring it into your real
17 life. If there is a problem with a phone that has an
18 exploding battery and you can't figure out how to fix
19 that I think most of us probably don't want a
20 refurbished one of those at this point. So again,
21 this same kind of thinking.

22 Now from our perspective in the VA we're

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1 very much trying to imagine life cycle management of
2 amazingly robust and complex technologies. And we
3 understand that many of the manufacturers they test
4 these in the environment as they know it and
5 understand it but it is almost impossible for somebody
6 to think of all the ways once we bring it into a
7 myriad of hospital systems that that device is going
8 to interact with the environments that are now facing
9 it. So I kind of call that the complexity of bringing
10 these devices in here.

11 We feel that the biomedical engineering
12 community along with clinicians are going to be an
13 amazing set of eyes and ears to tell you how those
14 things are engaging and interfacing with systems in
15 unexpected ways as well as expected ways. So in many
16 instances we do have an expectation that the
17 manufacturers are going to bring in devices and they
18 will be the people who will put those into our
19 systems. But we also have seen instances where the
20 manufacturers themselves have not always put them in
21 correctly despite their own people or their own
22 contractors. And really our own biomedical engineers

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1 are the ones who were able to find that and really do
2 the deep root causes which then inform our own
3 systems.

4 So that again is very much, it is a high
5 level view I know but it is the sense of how we're
6 trying to think of these things and learn from them.

7 I'm going to end just very quickly with the
8 sense of from our perspective transparency is critical
9 for us both in what the manufacturers believe their
10 designs are, our ability to learn from what they think
11 is imperative for how their systems work. We then can
12 look and say how is this applying, is it working as
13 you expected, that key question that we often don't
14 ask.

15 And then we want to report systems back up
16 and we think it is imperative to create better
17 reporting systems across that continuum and life cycle
18 so that we learn from refurbishing, we learn from what
19 doctors are seeing. I still worry that when we say
20 we're not seeing enough examples of how equipment
21 fails either as it comes into the system new or how it
22 gets brought back in once it has been fixed,

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1 refurbished, reused, is more a lack of awareness and
2 thinking about this device isn't working as it is
3 supposed to rather than a lack of problems with the
4 devices themselves.

5 Again from the clinician's perspective I was
6 never really taught to think this way about is this
7 device working as expected. And so as an ER doctor if
8 you give us an ultrasound we'll break it in a day
9 because we are like a bunch of children but if it
10 breaks early is that because I misused it, I
11 miscalculated it or is there really a problem within the
12 device itself. I wasn't taught to think that way and
13 we are very much trying to redo our thinking to say
14 the simple question in a complex world is this device
15 working as anticipated, as designed, as we thought it
16 would. And if not how do we get the wealth of
17 experience internally and externally reporting it
18 through systems which I think transparency is critical
19 to make it work better.

20 And I'll stop there.

21 MR. BRULEY: Hi, I'm Mark Bruley with ECRI
22 Institute. I'll give a few perspectives before we get

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1 another set of thoughts from Scot Mackeil from the
2 clinical, the setting itself and the Biomed programs.

3 In regard to adverse events, accidents,
4 injuries and deaths with medical devices based on the
5 work I've been reading and doing over the decades
6 about 80% of the adverse events are caused by you name
7 it whether it is user error, use error, or what I call
8 the technique of use and as opposed to issues related
9 to servicing, maintenance, refurbishing and so forth.

10 One of the things that Dr. Hemphill and Pat
11 Baird just mentioned was about consistency in
12 reporting and getting better data and information. It
13 may have been forgotten but about eight years ago AAMI
14 had a committee on establishing a uniform taxonomy for
15 labeling the types of repairs that were needed for
16 medical devices. I was on that committee. And
17 perhaps that could be reinvigorated if another AAMI
18 committee wants to take a look at that again. And it
19 was developed in collaboration with some of the FDA
20 staff that are in CDRH.

21 The inspection and preventative maintenance
22 of medical devices has been interesting in its

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1 development over the years. One of the things that I
2 think has really advanced the safety of medical
3 technology in the clinical setting has been the
4 education and certification of biomedical engineering
5 equipment technicians by AAMI over the last 20 years
6 or more. We now have I forget how many thousands of
7 certified biomedical engineering or equipment
8 technicians in a variety of subfields including
9 clinical lab and I think there is radiation as well.
10 And those certifications and that education has gone a
11 long way to I think prevent adverse events that may
12 have been caused by inappropriate service in the
13 clinical setting itself.

14 One other thing to consider when you are
15 looking at a medical device and its failure as Dr.
16 Hemphill had suggested in being able to destroy an
17 ultrasound probe within a day when we investigate an
18 adverse event we consider four basic interfaces
19 between the device in question and the rest of the
20 world. We consider the interface between the user and
21 the device where the device this is mainly for capital
22 equipment but it can also be applied to the single use

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1 disposables, the interface between the device and the
2 user where the user programs it or applies it to the
3 patient for monitoring care or therapy and in many
4 cases the device provides information back to the user
5 concerning the patient's status or other diagnostic
6 information. There is then the link between the
7 product itself and the patient which is a variable
8 biological system. The device provides diagnosis of
9 therapy and treatment, sometimes the patient provides
10 information on biophysical signals back to the device.
11 But then with the exception of a tongue depressor can
12 you think of a single medical device adverse event
13 that involves a single stand alone medical device.
14 What about a Pulse Oximeter? You have the piece of
15 capital equipment, you have connecting cable which
16 could be made by a third party, you have the probe,
17 those are three devices from three potentially
18 different manufacturers. A critical care ventilator
19 with the heater humidifier, the ventilator, the trach
20 tube and then the big piece of capital equipment.
21 Virtually all medical devices used in the clinical
22 setting are connected to some other medical device.

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1 And the cause of the adverse event has to consider
2 whether it was, in fact, the accessory device from a
3 different vendor that caused the adverse event.

4 And the fourth interface aside from the
5 user, the patient, the accessory devices is the
6 hospital setting itself which frequently provides
7 unique power, water, treated water, and sometimes
8 unique reprocessing and sterilization conditions for
9 that product. If you take the medical device out of
10 that system of four interfaces and simply test it in
11 most cases in our experience it checks out fine and
12 works according to specifications. So when we analyze
13 problem reports that come in to ECRI Institute or that
14 we look at in various databases we consider those four
15 interfaces when trying to assess what bucket that
16 report may go into in regard to a generic range of
17 causes.

18 So I'll stop there. I do want to touch base
19 with the AAMI people later about the work that was
20 done eight years ago related to the taxonomy. And
21 please see me afterwards. And if you don't have the
22 information, this predates Mary's coming at AAMI. I

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1 can get it to you.

2 Scot?

3 MR. MACKEIL: Okay. Thank you. I'm a
4 little out of my element here because we are not
5 wearing hats, masks, and blue pajamas today. But as a
6 Biomed in a thousand bed academic medical center I'm
7 taking care of 66 to 70 something ORs depending on the
8 state of closures, renovations. And I carry what is
9 called the BAT phone, the Biomedical Assistance
10 Telephone. And I am responding to the needs of
11 caregivers immediately in real time. We have a team
12 of biomedics that I can call over a voice IP(Internet
13 Protocol) device and a kit will arrive in the room and
14 the doctor, nurse, anesthesiologist will be looking at
15 us for an immediate solution.

16 One of the most important tools that we can
17 have is the knowledge of these devices. We really,
18 really need complete comprehensive service manuals
19 because that's how we develop the knowledge that we
20 have to apply to the context of the problem and meet
21 the needs of the caregivers immediately.

22 We like to have a ready source of parts

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1 available for immediate use. For example I carry in a
2 pouch on my belt the flow centers for the Apollo
3 anesthesia machine and we'll actually if they have a
4 flow sensor issue and the screen is grayed out and
5 they are not getting gas values the anesthesiologists
6 get really antsy. So I can do that gas sensor, flow
7 sensor exchange in less than 30 seconds. And that is
8 very important because what I do for the
9 anesthesiologist and the anesthesia machines is an
10 example of what I would call the best practice in our
11 industry. I have full training from Drager. I have a
12 full set of tools. I have all the parts that I need.
13 I have a laptop loaded with diagnostic software. And
14 working on these anesthesia machines is a natural as
15 breathing, pardon the pun.

16 But in another scenario certain other pieces
17 of equipment, you know energy device X, the
18 manufacturer absolutely will not share their service
19 manual with me. I can't get into the service mode and
20 when I'm called to the room I said well maybe we can
21 reboot it, maybe it will power up and start and work
22 correctly. But that is not the service model that I

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1 like to provide to our caregivers.

2 So to me empowering -- being a biomed here
3 and asking our industry to empower us to provide care
4 for our caregivers and their patients is the most
5 important job that I can be doing because when I walk
6 into the operating room to provide assistance to the
7 doctors and nurses in support of their providing
8 patient care I'm standing there with them and standing
9 behind me are all of you. So I really need you all on
10 my team helping me and all the other biomedes like me
11 to do what we do.

12 And that is the most important benefit that
13 I could give the FDA and all of you today because by
14 helping me and my coworkers provide our services to
15 doctors and nurses and their patients we reduce the
16 risk to our patients that need our services.

17 So with that I will hand it back over to the
18 next speaker.

19 MS. SCOTT: Okay. Wonderful. So now we
20 will move on to our representatives from ISOs and I'm
21 going to ask maybe Ms. Legate if you'd like to start
22 out and then we will move -- oh, we are going to start

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1 out with Mr. Anbari. Excellent.

2 MR. ANBARI: No slides that is the good
3 news. Real briefly I'll try to get us caught up a
4 little bit. The Independent Service Organizations
5 that are represented on this panel are showing up on
6 the screen. They include myself, Wanda and Rob.
7 We've collaborated in advance of the meeting to try
8 and come up with a consensus view from our perspective
9 as Independent Service Organizations on how we look at
10 the risks and the benefits.

11 And I think as we've already established
12 through a variety of the stakeholder presentations and
13 the discussion here clearly nothing is more paramount
14 than the patient safety and positive outcomes from
15 their healthcare experience.

16 The devices have to be safe and they have to
17 yield positive outcomes. And I think the reality of
18 healthcare is that there are risks inherent every time
19 a device is invented, every time it gets used, every
20 time it gets services, every time it gets reprocessed.
21 And those risks are fundamentally the same risks
22 whether an Independent Service Organization is working

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1 with a device or whether a manufacturer is.

2 There is ample anecdotal evidence that we've
3 talked about previously. There's obviously some good
4 data to support the fact that ISOs and OEMs do an
5 equally good job at performing servicing events.

6 I recognize there is also some question
7 about whether there is underreporting that takes place
8 but the evidence in the data that exists today
9 certainly supports the fact that we do a pretty good
10 job as it stands today both manufacturers and
11 Independent Service Organizations. And in large part
12 that is due to the protocols that exist in a hospital
13 requiring self testing and testing of devices prior to
14 their use along with the quality systems and the
15 regulatory frame work that sits on the top of our
16 industries today.

17 In terms of the benefits a robust
18 competitive marketplace helps manage costs and I know
19 there has been discussion earlier today about the fact
20 that perhaps costs don't belong in this part of the
21 conversation. And perhaps reprocessing activities
22 don't belong in this conversation, certainly not for

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1 single use devices but for multiple use devices. And
2 I think the challenge that we all face as an industry
3 is balancing the fact that you can't just look at
4 risk. You have to look at the benefits and you have
5 to look at the overall system that these devices exist
6 within. So to suggest that cost is irrelevant when it
7 is fundamental to as a benefit of these third-party
8 activities in driving preventative maintenance and in
9 creating the funding so that there can be local
10 responsive service is really to not look at the issue
11 in its entirety.

12 Preventative maintenance does save lives.
13 Deficient equipment is detected and it can be
14 addressed before it causes harm to a patient. And
15 that competitive marketplace that we operate in is
16 what allows Independent Service Organizations to
17 provide more than just the repair and maintenance
18 services that they provide but to really help coach
19 end users, clinical engineers, and clinicians alike on
20 how they can most effectively avoid damage to
21 equipment and keep it in top working order.

22 That convenience factor of local service

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1 representatives can't be understated, not just from
2 the perspective of what my company does, but from the
3 perspective of imaging solution providers, from the
4 perspective of clinical engineering organizations both
5 in-house and out sourced organizations; local presence
6 matters and helps improve safety.

7 So taking an aggregate we look at it like
8 this. We think the evidence is less than convincing;
9 we think that there is clear evidence of the benefits
10 that Independent Service Organizations provide to the
11 healthcare system and to clinicians and that that
12 robust marketplace really manages itself and maintains
13 itself and drives out poor performers.

14 As has been stated previously and in a
15 number of presentations we think the key really does
16 lie in cooperation and in guiding the market as
17 opposed to regulating it or overseeing it with a heavy
18 hand. By promoting cooperation we think that we can
19 do better than where things are today which is in a
20 pretty good place.

21 The unintended consequences of regulation or
22 oversight that is applied improperly or without

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1 thorough thought put too much at risk for the benefit
2 that we believe exists based on the evidence.

3 And that really is the sort of consensus
4 view of the Independent Service Organizations.

5 Back to the moderator's table.

6 MS. SCOTT: Okay. Excellent.

7 So with that I'm going to hand it over to
8 the audience to ask if there are any specific
9 questions for our panelists at this time. Any
10 questions from the audience?

11 If you have questions please feel free to
12 come to the microphones in the middle aisles.

13 Q&A

14 MS. FEDERICI: Hi, Tara Federici with
15 AdvaMed. I heard Dr. Maisel state at the beginning of
16 the workshop that reprocessing of reusable devices is
17 outside the scope but Mr. Anbari brought in the idea
18 of single use reprocessing of single use devices. And
19 I would just point out that FDA agreed to add to the
20 MedWatch form a checkbox so that we could capture data
21 related to problems with reprocessing of single use
22 devices. So that might be an option that we should be

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1 thinking about in this particular instance.

2 I also have a question for Mark Bruley. You
3 cited today, your report, your analysis of adverse
4 events has been cited and I'm just curious if you can
5 explain the methodology of the report and then whether
6 you looked at adverse events reported by OEMs,
7 facilities and third parties?

8 MR. BRULEY: Sure. That was part of my five
9 minutes for later but I'll be happy to address some of
10 it now. We looked at -- all of our strategies for
11 doing the analysis is contained in our submitted
12 comments if those have been read. It says all the
13 text string and search terms that we use and we looked
14 at the MAUDE database using ECRI Institute's search
15 engine that we put on the MAUDE database. Considering
16 the size of that database it is very difficult to use
17 the FDA's online system for looking at large text
18 strings and then downloading the hits because you are
19 limited to 500 hits per search.

20 We looked at the health devices, alerts,
21 tracker database which covers recalls for medical
22 devices and potential reasons for them. We looked at

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1 the National Library of Medicine PubMed database. And
2 we looked at ECRI Institute's confidential contracted
3 investigations that we've been performing. But we did
4 limit all of this to the last ten years.

5 The data that are in the reports include
6 third parties, OEMs and the hospital as well.

7 MS. FEDERICI: I don't know if you are aware
8 but FDA just recently released a report saying 90% of
9 facilities aren't reporting --

10 MS. SCOTT: Can you move a little bit closer
11 to the microphone so those who are online --

12 MS. FEDERICI: I'm just curious if you are
13 aware that FDA just released a report stating that 90%
14 of facilities aren't reporting appropriately.

15 MR. BRULEY: Did everyone hear the question
16 about the FDA's recently released report suggesting
17 that 90% of healthcare facilities are not reporting to
18 the MDR MedWatch MAUDE system. I'm familiar with the
19 MedWatch system. I changed the reporting law in 1998
20 because had certain provisions in the original
21 legislation not been included the system would be dead
22 because FDA was going to be publishing hospital's

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1 names on the internet in regard to all the MAUDE
2 reports and that wasn't the intent of the original
3 legislation.

4 Subsequent to the MDR 1990 regulations there
5 was a development of the MedSun program. Are you
6 familiar with MedSun? Yeah. Which is a more focused
7 program, gives more feedback to the hospitals based on
8 the reports that they submit, similar to the NEISS,
9 National Electronic Injury Surveillance System that
10 CPSC (Consumer Product Safety Commission) runs for
11 consumer products. And so they are looking at a group
12 of hospitals that are more tied in to the concept of
13 reporting medical technology related failures with
14 capital equipment as well as with single use and
15 disposable products including reprocessed products.

16 As far as the issues of underreporting let's
17 look at that for a minute. If a manufacturer has any
18 inkling that an adverse event that has come in through
19 the MedWatch system or the MAUDE MDR system if there
20 is any inkling that the problem was related to
21 inadequate servicing by the hospital itself or a third
22 party or a faulty third party repair part it is in

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1 their interest and they have every incentive to state
2 so in their comments in the MAUDE report. It is to
3 their best interest to deflect attention to them in
4 their design and marketing of that product. So I
5 don't see that there from a standpoint of
6 manufacturers underreporting that they are
7 underreporting in that regard.

8 In addition it was mentioned earlier today
9 and sort of glossed over that there is supposed to be
10 routine analysis of the manufacturer's service records
11 by the manufacturer themselves. Well, if that is
12 being done and if the analysis is properly assessing
13 whether a need for service related to a problematic
14 servicing could have caused or contributed to a
15 patient injury or death then why are they not
16 reporting it themselves; they can do so voluntarily.
17 They do not have to have report initially coming from
18 the hospital in order to report to the FDA MAUDE
19 system.

20 So unless there is someone else out there
21 that has done a lot of data searching I don't know of
22 any other database that is available with data yet

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1 that can be compared and contrasted to the work that
2 ECRI Institute did this year and what I did 19 years
3 ago for the previous conference on this.

4 MS. FEDERICI: Well, I invite my colleagues
5 to comment. Part of the challenge is if OEMS are not
6 getting those reports --

7 MR. BRULEY: Can you speak up for the
8 microphone.

9 MS. FEDERICI: I invite my colleagues to
10 comment. Part of the challenge is OEMs aren't getting
11 those reports either.

12 MR. BRULEY: My comment was about the
13 service records that they have in their own system
14 that can be another source of data.

15 MS. SCOTT: And I think Scot wanted to --
16 I'm sorry, we'll let Hans go and then Scot you had a
17 comment as relates to the last question.

18 MR. BEINKE: Yeah, I would agree with that.
19 We are analyzing our service reports. The issue is
20 when we're now out of the service picture and we don't
21 have visibility to that. So the report that you've
22 done honestly I haven't gone through it to look at the

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1 methodology. I'm hard pressed to believe it includes
2 all events. And I will also go on to point out that
3 industry is not interested only in things that lead to
4 harm and injury. We are interested in other MDRs, we
5 are interested in trending. And unless we have links
6 to all this information we can't do what we are
7 required to do. And it is not just what we are
8 required to do; it is the bottom line of what that
9 leads to which we've all agreed on which is the safety
10 to the patient.

11 MR. MACKEIL: You know speaking from the
12 level of the workbench I've been a biomed for a long
13 time and I know a lot of biomed. And when it comes
14 to getting involved with things like the safety
15 reporting system in the hospital knowing what the
16 MAUDE database even is, knowing that the Safe Medical
17 Device Act even exists you know for a lot of biomed
18 that are working today it is so far down on their list
19 of concerns and priorities because you are really
20 working hard to keep up to get to the next service
21 call to take care of the next piece of business. The
22 demands are absolutely incredible. And I've been

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1 online looking at the MAUDE reporting system and it is
2 not the easiest thing in the world to do.

3 In the hospital we have all this mandatory
4 education that we have to do, blood borne pathogens,
5 fire safety, all this other stuff. It is amazing what
6 you have to do to meet your annual education quota and
7 then you start getting the nasty-grams. You haven't
8 filled out your health stream documentation.

9 If we really want to get this data from the
10 workbench up to this level I would suggest we have to
11 do more education that penetrates much deeper to the
12 level that I work at and maybe come up with an easier
13 to use system that looks more like a work order that
14 biomedics are more familiar with. I hate to say it but
15 I could do a much better job reporting on things that
16 I see and I know about the MAUDE database and where it
17 is. But a lot of biomedics just aren't there and if you
18 really want to improve this reporting I would suggest
19 that the FDA go there and start working with biomedics
20 and raising awareness of this. I don't know of a
21 hardworking biomedical engineer that if you explain
22 the necessity and the reasons that they wouldn't

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1 become diligent about doing this type of thing.

2 So that is the comment that I would put
3 forth. And if anyone has anything else to say on that
4 line I'd be interested in hearing it.

5 MS. GEORGE: I was going to actually
6 continue in this topic so if I could interject because
7 I do like your idea of what you are saying. I'm
8 Elizabeth George with Philips.

9 One of the things that I am just curious
10 about from not from the OEMs because I know their
11 answers but as an OEM one of the things we have
12 obviously we have our MAUDE reports but that is a
13 really tiny, tiny, tiny, tiny bit of information that
14 we have as a manufacturer. We have all of our service
15 reports which talks about installation, which includes
16 all those issues that you talked about when we screw
17 up when we install it; it includes all the parts that
18 we replace. We do trending on that. Every time a
19 hospital calls us and says this doesn't work we have a
20 complaint we have reams and reams and reams and reams
21 of data on our own products. And only a miniscule
22 amount of those go to the FDA as a MAUDE report. But

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1 when the FDA comes in and looks at us the first thing
2 they do is pull that data and they ask have you been
3 trending it. And 90 -- I'm probably off, at least 75%
4 of our recalls if not more have nothing to do with a
5 MAUDE report; they are a trended issue for a failure.

6 So the question I actually have for you guys
7 is just what you are saying is how can we get that
8 data of all the wonderful service activities, the
9 fabulous highly qualified service people are doing
10 work but we don't know that you are replacing parts
11 because you may be buying them from us or from
12 somebody else. We don't know that you've serviced
13 that part. And that data you only have a slice of the
14 data on that product. We have all of the places that
15 you are not working on and that might be the amount of
16 data that could tip us to fix or improve the quality
17 of our product sooner.

18 So I am just curious as to what your
19 thoughts are on how keep the FDA out of it, they don't
20 need to get all that data, they don't want all that
21 data. They get enough data as it is. The
22 manufacturers would like to have that data to help

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1 improve the quality of the product, make the issues
2 better, maybe help you guys service it better.

3 DR. HEMPHILL: I have a simple thought but
4 I'm an ER doctor so we try to keep things very simple.
5 So something that we've tried to do is we are really
6 trying to understand how you help people report,
7 report anything. And so to the point made by Scot is
8 if the reporting system is hidden and you can't get to
9 it, you are not going to get reports. And if it is
10 hard to use because its 30 pages long you are not
11 going to -- people just say never mind.

12 So we try to have an entry system into
13 reporting for the VA that is based on a couple of
14 pretty simple concepts. One is is it an adverse
15 event. But we also do near miss. So we are really
16 trying to redo people's thinking so you say you know
17 dodged a bullet or wow, better lucky than good, which
18 is a mantra we have. You start saying that was a near
19 miss, not just wow we got away with it, that is a near
20 miss. And the next question then is to prime people
21 to say was this related to a device you were using and
22 if so, check the box. So simple form to enter, easy

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1 to get to, check the box it might have been related to
2 what you were using and now you already have the
3 ability to say okay let's go dig deeper.

4 Now do we share that with -- I mean if we
5 find enough concern then yes we put those into our
6 MAUDE MedSun and other databases so that it can get up
7 and then we engage very quickly with the FDA to say
8 are you seeing this, what are you seeing and try to
9 help us with this.

10 I don't have a great model for engaging with
11 the industry itself because the more you fracture your
12 time you really, there is just so much to be looking
13 at with each day. But again I think that if we have
14 ways to think about sharing that information certainly
15 we can share some with what we send to the FDA. We
16 will bring in manufacturers when we are really
17 concerned and try to begin that conversation early
18 because we do have an awfully big system to look at to
19 try to help figure out trends early on.

20 MR. BRULEY: This is Mark Bruley again. To
21 Scot's point about the process of reporting they do
22 have to differentiate that from a patient safety

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1 standpoint certainly almost all adverse events may
2 have some aspect of risk to patients as it relates to
3 cause or contributed to specific injury or the
4 potential for an injury. But to the reporting issue
5 biomedes would have to go through and should be going
6 through the risk management departments at the
7 hospitals. And they work in collaboration with risk
8 managers and those haven't really been mentioned here
9 yet. The role of risk manager in reporting to the
10 FDA, that is where most of the reports come from from
11 the field itself. The injuries and deaths are
12 separate from malfunctions. Now malfunction may well
13 be related to improper service as we've seen with
14 perhaps some of the anecdotes here. But if you are
15 talking more about patient safety you are really
16 looking at the injuries and deaths. And although we
17 looked at all issues as it is pointed out in our
18 submitted comments to the FDA and our strategies for
19 doing that. But from a process standpoint the biomedes
20 typically do have to collaborate with risk managers to
21 get the reports to FDA whether it is with the MedSun
22 hospitals for which I think there are 316 hospitals

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1 that are bought into that system or it is with the
2 rest of the healthcare institutions across the
3 country. So if you are talking about potentially
4 educating on better reporting you need to include risk
5 managers.

6 MS. SOCTT: We are going to take one more
7 question from the floor, then I have a question from
8 online and then we will jump back to the floor again.

9 MR. LIPSCHULTZ: So I submitted this
10 question via an email, then I realized you were going
11 to do it on a microphone so you may be able to pull
12 that one out of the queue if that's where it is.

13 MS. SCOTT: Okay.

14 MR. LIPSCHULTZ: This question is primarily
15 for the manufacturers.

16 MS. SCOTT: Could you state your name and
17 affiliation. I'm sorry.

18 MR. LIPSCHULTZ: Oh, I'm sorry. Alan
19 Lipschultz, President of Health Care Technology
20 Consulting and I come primarily from a clinical
21 engineering background. So this is really aimed at
22 the manufacturers particularly looking at those

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1 products for which there is not a complete service
2 manual that is available to third party servicers.
3 And the issue is that when you become aware, actually
4 it applies to all manufacturer when you become aware
5 of parts that third party servicers are replacing in
6 the field with non-manufacturer parts that is causing
7 a problem A or B but they are doing activities that
8 you didn't recommend or maybe because there is a lack
9 of information in the field and that users are doing
10 and that you are seeing is causing a problem with your
11 devices then you have a residual risk that should play
12 into your risk management strategy. And if there is a
13 residual risk then you should have some sort of
14 strategy to mitigate that risk. And I'm questioning
15 whether or not there is a way -- any reason why you
16 then couldn't issue a service advisory or safety
17 advisory not aimed at clinicians but aimed at the
18 people who are the root of the problem, namely you
19 have third party servicers that gives them information
20 in terms that we are aware that a particular part is
21 being replaced by and some of these are available if
22 you look at the advertisements you can see which

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1 companies are advertising parts to replace yours, my
2 point is if the people who are doing the service in
3 the field are aware of the risk involved with it then
4 they may think twice about it and that is a way for
5 manufacturers to mitigate the risk.

6 Second comment/question regarding making it
7 easy to report problems in general. The only way from
8 -- that I see to do that is to start talking about
9 standards in terms of how we code problems as third
10 party servicers. It is coded in a standardized manner
11 and have data interchange protocols to be able to say
12 that this is something that should be reported to the
13 manufacturer, let's shoot it off, we had a service
14 event so that the right information goes automatically
15 to the manufacturer and you don't have to start then
16 retyping it all into a whole separate form. And these
17 protocols can be set up in advance; work through the
18 risk management department it is not being worked
19 exactly how you'd do it but you can make it automatic
20 and it is a lot easier to make it work.

21 MS. SCOTT: Go ahead. Scot.

22 MR. MACKEIL: You know that is an excellent

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1 point when you talked about coding and standards. You
2 know if we are trying to identify, track and trend
3 service error events I could see where that would go
4 but how would we turn that into a way to educate my
5 colleagues about how to recognize what is a service
6 error event and what level of service error event is
7 reportable. It is a very large broad topic but if it
8 was properly defined and standardized I know I could
9 do it. And I do think it is an important thing
10 because we recognize and code different types of
11 reports now. But you know service errors that one
12 needs some work.

13 MS. SCOTT: Did any of our panelists want to
14 tackle the first part of our participant's question.

15 MR. BEINKE: The question about the
16 advisories I think is what -- is that what you are
17 referring to?

18 MS. SCOTT: Yes.

19 MR. BEINKE: I mean I think we would be
20 hesitant and I'm speaking for my company to send out a
21 general advisory for kind of an incident over here or
22 an incident over here. I think that would create a

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1 lot of confusion and suggest a general problem. So
2 our issues are more one offs and how to communicate on
3 that specific issue. I think we do, you're right,
4 have an issue of needing to communicate the problem
5 that goes with some of these unapproved parts or
6 improperly validated parts. But in terms of an
7 advisory I think generally that probably doesn't make
8 sense unless we see that there is a general trend to
9 use X instead of Y.

10 MS. SCOTT: Okay. Anyone else from our
11 panel who would like to address that question; the
12 last question?

13 Okay. I'm going to jump to a question from
14 online.

15 We have Tom Quinn who is the President of
16 MRA and his question starts out with the MITA
17 representative and some OEMs are reporting safety
18 issues involving ISOs. His question is did these OEMs
19 or MITA file a 3500, a radiation overdose form, a
20 trade complaint or any notification of these safety
21 issues which are of such importance in this workshop?
22 If not, why?

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1 MR. BEINKE: I mean again that's a very
2 general question and I think it depends on the
3 specific situation. Again speaking for my company
4 when we have some of these events I would not say
5 generally but we have filed trade complaints when we
6 think that it is significant enough or we have
7 communicated with the so-called offenders.

8 I don't know if anybody else from industry
9 wants to comment.

10 MR. BRULEY: I'm not from industry but the
11 question ties into the comment I had that there is
12 nothing keeping manufacturers from based on their own
13 analysis separately reporting service related errors
14 to the FDA via MAUDE or any of the other avenues.

15 MS. SCOTT: Okay. I did see some people
16 standing in the back of the room so I'm going to jump
17 to our back microphone.

18 MS. KAY: My name is Janet Kay (ph) and I
19 work for Intrega Life Sciences and we would be
20 considered an OEM in this conversation. So for the
21 ISOs we've actually had some great engagement with
22 ISOs ourselves with my company and we think they do

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1 provide a great service. We do struggle a little bit
2 with the things we're talking about training, using
3 validated parts, we like you guys to use parts that we
4 use in our products as we validate with. So for those
5 gentlemen that are on the board or on the panel that
6 are from the ISOs what are your thoughts about quality
7 agreements; you working with the OEMs to develop a
8 kind of agreement with that OEM so one we know who you
9 are, we know what products you are working on that are
10 outs and then we could work towards agreements about
11 how you get trained, recertification on your training
12 and that you are using validated parts. Your thoughts
13 on that?

14 MR. ANBARI: So I mentioned in the
15 stakeholder presentation that I did that we have
16 approached over our 40 years of business virtually
17 every major manufacturer of instrumentation and
18 devices in the marketplace to try and establish some
19 form of a partnership. In some cases that has
20 resulted in our ability to buy parts directly from
21 them. In 99% of the cases it's resulted in no, that
22 is too much of a direct threat to our commercial

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1 interests, we need to maintain our devices because
2 that's what we do. We have piloted very strong
3 strategic partnerships on very complex devices with
4 manufacturers where we essentially said because your
5 market share Mr. Manufacturer is so low when we have
6 our customers come to us out of convenience and out of
7 availability because we are there in the hospital
8 everyday and bring us one of your devices we would
9 like to be able to send that to you directly. We are
10 happy to pay whatever price you tell us we need to pay
11 and we're going to handle it as a pass through with
12 our customers. And the reason that we wanted to do
13 that was because of the convenience and the overall
14 relationship with the healthcare provider facility.
15 Unfortunately within 90 days of establishing
16 relationships like that they end up going wrong and it
17 is largely because of sales and commercial interests
18 on the part of the manufacturers.

19 I will tell you any manufacturer that would
20 like to work with us to establish that type of
21 relationship we are more than happy to have those
22 conversations and by no means certainly should those

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1 be considered to be exclusivity. And that is not a
2 sales pitch, that is simply saying our industry as a
3 whole speaking at least for the surgical device repair
4 companies I think we are all wide open to finding ways
5 to work with manufacturers and some of us; to be fair
6 about it a number of my competitors do have some good
7 relationships. We just haven't been able to get one
8 that has lasted.

9 MS. KAY: Do you have a comment, sir?

10 MR. MOOREY: Actually I do. I've been in
11 this industry for a long time, worked for some of the
12 larger Independent Service Organizations. I can tell
13 you these are already happening; they've been
14 happening for my entire career. It is in our best
15 interest to seek out those people that are going to
16 have the biggest impact on our customers and find ways
17 to work collaboratively. And I can tell you we have
18 some very strategic partnerships where the OEM is
19 actually sitting at the table as part of my team in
20 some of these discussions. So that is where we are in
21 healthcare today. We have to have those types of
22 relationships; it can't be us or them. Many of the

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1 OEMs are realizing that they need us and part of their
2 strategy for service is by utilizing our local
3 service, our local talent. So I'll tell you there's
4 already in place, we are already working through that.

5 MS. KAY: That's great. May I have a
6 follow-up?

7 MS. SCOTT: Yes, go ahead.

8 MS. KAY: So then if that is true for the
9 biomed are you guys doing anything on the hospital
10 side then to ensure that when --

11 MS. SCOTT: I'm going to ask that you speak
12 into the microphone though so people online can hear
13 you. Thank you.

14 MS. KAY: I apologize. So is at the
15 hospital side though with biomed then are you doing
16 anything on your side as these ISOs are coming into
17 your hospital because you know people are coming and
18 going in hospitals all the time. Are you aware of who
19 is touching equipment and that person that is touching
20 that equipment is truly certified to touch that
21 equipment?

22 MR. MACKEIL: So one of the interesting

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1 duties that I perform are what I call vendor support
2 and escort calls. And it is a pretty common thing and
3 it is usually originated because I've had a service
4 call encounter with a caregiver on a piece of
5 technology and we've decided that the solution to this
6 problem is to bring in the manufacturer to repair the
7 device. So I've already talked to that rep on the
8 phone. It is usually somebody that I know very well
9 and have had a long standing relationship with,
10 someone like Dave Young from Philips who takes care of
11 my IE 33s, the hardest work in biomed in the world by
12 the way and Dave shows up, I get him into scrubs, we
13 bring him to the cardiac OR and we deal with this
14 problem. And I may have to go off and do a couple of
15 other things but when he calls me and says Scott, it
16 is all set, all right, Dave, I'll meet you back there,
17 you can run me through it and I'll sign your service
18 order. So after I sign his service order I have to go
19 close the work order that I opened to call him on and
20 I'll type in a description of what Dave did.

21 So we are very closely monitoring what our
22 third parties and manufacturers and ISOs are doing.

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1 But I treat them equally regardless of what badge they
2 are wearing. I work with them. I make sure that they
3 are doing what they are supposed to do. I support
4 them. I get them stuff. You know I get them in, I get
5 them out. I help them with parking. In some cases
6 just the other day one of my C elements went down
7 because the pendant broke and the pain management
8 doctors were frantic because they need this C element.
9 I called up my rep and I said I've got a broken
10 pendant, I know we are under contract. He drove by
11 the hospital with a pendant. I ran out and grabbed
12 it. And he talked me through it on the phone how to
13 install it and we did the whole work order and
14 paperwork trail, so yes, we are really watching what
15 is going on and making sure that the right things
16 happen and all the documentation is done. I mean that
17 is something that is common in my workday.

18 Does that answer your question?

19 MS. KAY: It does. Thank you very much.

20 Thank you.

21 MS. SCOTT: Wanda, do you have a response.

22 MS. LEGATE: Can I just touch on the first

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1 part of her question about the quality metric with
2 ISOs and things like that. You know we're from the
3 parts industry. So but I can tell you that we have
4 high quality metrics with our customers. They are
5 requiring that of us. So for example if we go into an
6 agreement with a customer, one of the first things
7 they ask for what is going to be your DOA (dead on
8 arrival) rate. I think the biggest thing as I've
9 listened to all of this is around the ISO you'd be
10 surprised how many independent companies are going
11 through ISO certification or have already been there.

12 And so when you talk about the CAPAs and things like
13 that, we are already doing those things. So I think
14 we are a lot further along than I think maybe the FDA
15 realizes and maybe some of the OEMs realizes. But at
16 the end of the day we do have those metrics or we
17 wouldn't be in business.

18 MS. SCOTT: Okay.

19 MR. BEINKE: Can I ask a question?

20 Yeah, I have no doubt that you are far along
21 and many of you are. The question I was more
22 interested in is the upfront part, not the monitoring

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1 part and watching what is taking place and make sure
2 that it is appropriate, but you know in industry we
3 refer to it as supplier controls. So you pick an ISO
4 and what is the process for qualifying that ISO. So
5 you can have a certification. I mean a lot of times
6 people talk about oh, I'm ISO certified but that
7 doesn't necessarily mean that they have the specifics
8 for the service or the product that they are providing
9 so I'm just curious as to how you go about supplier
10 controls, the ISO being the supplier to the hospital.

11 MS. LEGATE: Well, for us being a supplier
12 to hospitals, most of the hospitals have their own
13 quality management system. We have to pass those
14 requirements just like we do with OEMs. So we
15 currently do business with several of the OEMs and we
16 went through their quality process, we are actually
17 going through stage two of our ISO now. We are still
18 a young company. I have been in this business for
19 over 25 years. The previous company that I worked for
20 we've been 13485, ISO 9001 so I think all of that is
21 mandated by our customers which are the ISOs that are
22 going through quality. But also the OEMs; we do a lot

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1 of business with OEMs.

2 MR. BEINKE: So they would provide
3 documentation that they have training for this
4 product, that product and the next product?

5 MS. LEGATE: Absolutely. Again I'm just on
6 the parts side of the business. I'm not on the
7 service.

8 MR. BEINKE: Yeah.

9 MR. MOOREY: I'll add to that. I'll say
10 hospitals are already required to ascertain the
11 competency of people doing work in their facilities.
12 That is part of requirement for regulatory
13 accreditation. So they are already going through that
14 process. In my particular case my company and some of
15 my competitors sitting in the audience today we sit in
16 the place of our customers. So instead of them having
17 somebody do that we take on that responsibility and we
18 absolutely have the responsibility to ensure that
19 folks we are using meet those requirements within that
20 hospital so that they can receive their accreditation.

21 MS. SCOTT: Any other comments from the
22 panel? Scot?

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1 MR. MACKEIL: Yes, you know the
2 qualifications of vendors is something that takes
3 place at a little higher level than where I sit but I
4 know we do have extensive controls we use the Vendor
5 Mate Process, everybody

6 has to be vetted. And at my particular
7 level when I go on a vendor escort and support call
8 the relationship between the company and myself has
9 already been well established. But I know that there
10 are significant controls in place at the
11 administrative level. And it is pretty rigorous where
12 I work. We just don't let anyone in the door. But
13 the relationships we do have with both manufacturers
14 and third parties are absolutely essential to what we
15 do and we really definitely need to make that better.

16 MS. SCOTT: Okay. We are going to move back
17 to our audience for another question.

18 MR. LESLIE: I'm Mike Leslie. I'm Vice
19 President of Regulatory Compliance and Quality for
20 Roche Diagnostics here in the U.S. And as I've
21 listened to the first panel discussion this morning
22 and then this panel this afternoon I've heard about

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1 four things that I think are very kind of repetitive.
2 And so first thing a lot of good dialogue and I have
3 not heard a single thing that I've really disagreed
4 with from an opinion standpoint so that's good.

5 One of the things though that I keep hearing
6 is an issue around competitive advantage or
7 disadvantage with the OEMs and the ISOs. Another one
8 is associated with cost. Another one then is around
9 the data that would justify change. And then the last
10 one is everybody is agreeing that patient safety is
11 number one.

12 So I guess as I look at the purpose of being
13 here today and what we're trying to accomplish the
14 first one around competitive advantage or disadvantage
15 really the FDA had no oversight and really very, very
16 little care into the competitive landscape that is out
17 in the marketplace. So to me it is kind of not worth
18 talking about any further.

19 The second thing when I look at the cost we
20 are absolutely right. This is the medical device
21 industry. You know we are not manufacturing bottle
22 caps, picture frames, bicycles; this is an expensive

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1 industry. People rely on these devices to sustain or
2 to help them live healthy lives. And because of that
3 there is going to be cost associated with it. The FDA
4 exists for a reason. That oversight is there for a
5 reason to protect public health. And that is not
6 cheap for anybody to do.

7 The last one then around issues with saying
8 to .005% or whatever and that OEMs do well, the ISOs
9 do well, then I'm -- my next question is do we
10 regulate everything. So why not all post-market
11 support? Why are we doing anything if everybody does
12 everything okay now? Which the FDA, of course, is not
13 going to agree with.

14 So my point to this is that if we are really
15 doing that good as an ISO provider or from an OEM
16 provider I don't understand what the issues are of
17 being registered with the FDA, having a compliant
18 quality system, following the QSRs, all the reporting
19 accountabilities that are there so that we can all
20 ensure patient safety. That's what we are here to
21 talk about.

22 And the competitive landscape, the dollars,

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1 all of that, yeah, that is true but that is not the
2 focus. The focus is patient safety. The FDA holds
3 the OEM manufacturer accountable for that device no
4 matter who works on it. So our ability to know where
5 that device is, what's happened to it, any spare
6 parts, any issues, the FDA doesn't look the other way
7 and say oh, well, hey, an ISO was taking care of that
8 instrument, well, you don't have to worry about it
9 anymore. ISOs play a very vital role in the
10 healthcare of the United States. For the smaller
11 medical device manufacturers, there was an example
12 earlier where you don't have the resources; you do
13 have to partner with an ISO organization. But the FDA
14 doesn't say okay, well, you know what since they're
15 providing that service you are off the hook for MDR
16 reporting, you are off the hook for trending parts and
17 complaint investigation and corrections and removals
18 because this other company does it; that is not the
19 case and it never will be the case. So everybody
20 playing by the same rules so that we can make the
21 overall health system better and compliant and help us
22 generate more input into better designs and more

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1 technology is what we should all be here for.

2 So I don't understand what the issue is of
3 having a compliant quality system in your
4 organization, being registered with the FDA and being
5 open to the same audits and same scrutiny as everybody
6 else. I don't know why we are stuck on that. And if
7 you could help answer that I would appreciate it.

8 MR. ANBARI: Yeah, I mean look I think as a
9 practical matter if you are going to impose oversight
10 and you are going to impose rules that are the same
11 rules that apply to a manufacturer you also have to
12 level the playing field with respect to the technology
13 that is available to Independent Service Organizations
14 to deliver the service. And if that means making
15 parts available, documentation available, reporting
16 available to the third party in addition to the third
17 party making reporting available to the OEM; it is all
18 helpful. And it is one way that this could be
19 approached.

20 But the bottom line is that without -- when
21 you impose the oversight without also addressing the
22 structural changes that effect the level of

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1 competitiveness and competition that is in the market
2 hospitals will spend more for, in their total cost of
3 ownership, for equipment. It will cost them more to
4 repair it. They will be driven to replace it more
5 regularly as they reduce preventative maintenance on a
6 regular basis. And frankly they are going to be forced
7 in, we've seen it time and time again, they get forced
8 into upgrades of perfectly good equipment because a
9 manufacturer has decided we've moved on to the next
10 generation now, we think it is better, and we are
11 telling you Mr. GI doctor you'll be able to find
12 polyps better because they are high definition. I
13 mean that is the practical reality of how the
14 competition comes into play. And oversight and
15 regulation will have a cost. And I think that is
16 really what the fundamental question is is we're
17 balancing those costs and those benefits.

18 MR. LESLIE: But again the competitive piece
19 FDA doesn't have jurisdiction.

20 MR. ANBARI: They have to have.

21 MR. LESLIE: They don't have jurisdiction
22 over that.

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1 MR. ANBARI: No, the point is if you look at

2 --

3 MR. LESLIE: I don't disagree with what you
4 are saying; so fine the ISO then you are going to
5 maintain this piece of equipment for the next ten
6 years that the manufacturer is not responsible for or
7 is no longer supporting. How is that not still
8 subject to post market review and MDR reporting, any
9 corrections, anything else associated with that
10 instrument. That is what we are talking about. That
11 is what we are talking about the regulations covering,
12 making sure that all of that data continues to flow
13 into both industry and into the Agency.

14 MR. ANBARI: Yeah, I mean changing reporting
15 requirements and saying you should report whatever the
16 event is or whatever it might be, that is one of those
17 potential outcomes from this process. And I think
18 that is part of what people are exploring.

19 MR. BEINKE: Can I make a comment on this
20 regulatory oversight. We've said it I don't know how
21 many times today but we haven't really said what that
22 means. I think the FDA has some flexibility in terms

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1 of what that looks like. There are various costs for
2 registration. FDA looks at risk base and determines
3 what their inspection schedule is going to be. So if
4 you are making pacemakers it is one thing, maybe if
5 you are service providers it is something else. So I
6 find it a little bit difficult to understand this fear
7 of the unknown. I mean it has not been defined and so
8 I'm not sure at this point what that cost implication
9 would actually be and I think -- I guess I have some
10 trust in FDA that they are going to hear all of this
11 and look at it and gauge what level is appropriate.

12 MR. MOOREY: Well, I'd like to add I'm not
13 sure where this perception comes that we are not
14 already regulated. I mean if you look at the
15 healthcare industry as a total I mean we have every
16 three years an inspection agency is coming in to
17 certify the hospital and the program that is being
18 run. In that is a flurry of policies and procedures
19 that we need to measure up to to show data that we are
20 complying to those things. We have the same
21 requirements if we are replacing a tube we have to
22 fill out the same paperwork, if it is a major imaging

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1 repair there is a physicist coming behind us just like
2 they do at the OEM to certify that device meets that.
3 There already is regulations. CMS is providing
4 guides, the state departments of health already
5 providing regulation. What you are talking about is
6 additional regulation. And the question is why? Where
7 is the data that shows that this is required?

8 MS. SCOTT: I'm going to jump in here. We
9 are going to get into more of the discussion related
10 to challenges as it relates to this overall issue on
11 day two in some of our other panel discussions. So I
12 do want to encourage us to refocus our questions now
13 in terms of the particular focus for this particular
14 panel discussion which are the benefits and risks
15 associated with refurbishing, reconditioning,
16 rebuilding, remarketing and remanufacturing and
17 servicing activities. So if we could refocus the
18 discussion to really focus in on the benefits and
19 risks at this point.

20 We will take two more questions and then we
21 are probably going to need to wrap up our session.

22 MR. GRIMES: Hi, my name is Steve Grimes. I

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1 am the principle consultant for Strategic Health Care
2 Technology Associates in the Boston area. And I've
3 been in this industry, clinical engineer for over 40
4 years now working either with probably about 20 years
5 Independent Service Organizations another ten years
6 working as a clinical engineer director of academic
7 health centers and also was probably another ten years
8 as a consultant. So I've had fairly extensive
9 experience on the supplier and the advising side. I'm
10 also involved in the AAMI standards group that Mary
11 Logan was referencing earlier that does equipment
12 management standards or establishes equipment
13 management standards. So one of the things we are
14 looking at coming up is the acquisition of medical
15 technology.

16 Couple of things that I just wanted to point
17 out is with respect to the benefits and the risks one
18 of the things I think is very important from the
19 standpoint of those of us who were involved as
20 healthcare technology managers running the programs
21 that manage the technology in hospitals and when I
22 talk about managing the technology, it is not --

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1 servicing is certainly a part of it but we are also
2 involved in the acquisition and the training and the
3 ultimate disposal of the technology. When it comes to
4 service it is important for me to be able to have
5 access to a wide variety of tools in terms of
6 resources, the manufacturer service, Independent
7 Service Organizations, in-house staff and I apply
8 those based on what I think the particular problem or
9 the particular issue warrants; what type of risk is
10 involved and what type of resources are appropriate to
11 apply to it.

12 One of the concerns I do have is I certainly
13 have seen that there have been regulations not put
14 forward fortunately by the FDA but other government
15 agencies have established regulations often without
16 having looked at the evidence to demonstrate that
17 there was in fact a problem that needed to be solved.
18 And as a consequence one of the challenges we face is
19 that we are having to apply resources that we could
20 otherwise use to address the real problems in our
21 industry, solving real issues, you know making the
22 environment safer to meet regulations which frankly

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1 often there's no real merit in addressing those
2 regulations. There is no evidence that again they are
3 really solving a problem. It is one of the
4 challenges.

5 And then just the other point that I
6 originally wanted to make is that there are -- I'm not
7 sure how familiar on the OEM side they are with
8 respect to the kind of documentation that we maintain.
9 All hospitals are required to maintain an inventory of
10 all of the medical equipment in their organizations
11 and the service on that medical equipment and in that
12 we include what parts are used on each piece of
13 equipment, the nature of the service and often code
14 the equipment as to what the nature of the service
15 was. Was it a maintenance related issue; was it a
16 user related or process related problem; was it a
17 spontaneous failure? Again the idea being each of
18 those problems has a different type of mitigation. If
19 it is a maintenance related problem then we change the
20 way we were doing maintenance or who is performing the
21 maintenance. If it is a use related problem then it
22 may involve some additional training. But these

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1 systems, these documentation systems do exist in each
2 institution. And there are perhaps venues that we
3 could look at in sharing this information. It
4 certainly would be beneficial I'm sure for the
5 manufacturers to have access to the kind of
6 information, the data that we collect. And I know
7 from my standpoint it would be useful for us to have
8 access to the information that manufacturers have in
9 terms of the service and reliability of their
10 equipment.

11 There are forums, PEMI has a, it was
12 mentioned earlier a supportability work group or task
13 force where manufacturers and members of the
14 healthcare provider community work together to talk
15 about how to effectively exchange information and
16 provide support of the technology that it out there.
17 And also the equipment management company that I was
18 referring to that is a part of the standards group
19 would be another example of another area that we
20 perhaps could talk about how do we come up with ways
21 of standardizing this information in a way that it can
22 be conveyed to manufacturers in ways that it would be

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1 useful to them but also perhaps make use of
2 information manufacturers would be willing to provide
3 us.

4 So that was my comment. Thank you very
5 much.

6 MS. SCOTT: Any comment from the panel?

7 Okay. We'll have one more question from the
8 floor in here. And I believe we also have another
9 question -- if there is anyone else online who has
10 additional questions please feel free to email those
11 questions to the email address that is posted online.
12 And we will take one more question from the floor and
13 if there are any other questions from those online
14 please feel free to email that question.

15 MR. RIDGWAY: Thank you. My name is Malcolm
16 Ridgway. I've been around for a while. I see an
17 opportunity to come together here. Just very quickly
18 not every piece of equipment if it is not working
19 properly and safely can injure a patient. So for
20 those items that have the potential to injure a
21 patient if they are not working properly and safely
22 what we can come together on is defining how to test

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1 that it is, in fact, working properly and safely and
2 then everyone who signs off after maintaining the
3 equipment for its scheduled maintenance or whether it
4 is repair will certify to the user this equipment is
5 working properly and safely according to the proscribe
6 procedure that we come together and put out there. I
7 think this will work. There is a complicated way of
8 doing that called failure modes and effects analysis.
9 But cut right through that there is a way of defining
10 a subset of equipment, call it critical equipment or
11 whatever you will and let's have an agreed set of
12 procedures on how you establish the safety and
13 performance effectiveness of that device and use that
14 as a test that the equipment is left the way it should
15 be for the user. And I would suggest that whether you
16 use manufacturer part or another part the proof test
17 that's a good part is whether or not you can bring the
18 equipment to the point where it is working properly
19 and safely.

20 And I think that is something both sides of
21 the house could get together and work on that.

22 Thank you.

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1 MS. SCOTT: Scot?

2 MR. MACKEIL: So Mr. Ridgway really hit the
3 nail on the head here. One of the things that I do in
4 my job is every day I have to face a doctor or a nurse
5 or a team leader and bring to them a piece of
6 equipment that's been in my lab at my workbench and
7 say Janice, it is all set. And she'll say in her
8 British accent, well thank you luv. Janice is one of
9 the toughest nurses in the world and she is a very
10 hard clinician to make happy. But that is part of my
11 job; that is what I do.

12 As a biomed I really depend on the
13 manufacturers providing me the documentation, the test
14 procedures. And one of the tough things is some of
15 these procedures aren't really that black and white,
16 they are difficult to follow on the workbench. I have
17 a certain set of industry standard test equipment and
18 I'm going to bring a piece of equipment out of my bag
19 here as an example just for fun if I can find it. So
20 this is a little test cable and I built this as a
21 result of reading a service manual and in the service
22 manual the manufacturer literally described how to

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1 build out of electronic components what most of us
2 know as an electrosurgical analyzer. It was written
3 like they didn't have a clue that biomed didn't have
4 electrosurgical analyzers out in the world. And
5 another piece in this bag this is brilliant, this came
6 from J&J and it allows me to plug into the front of
7 their harmonic scalpel, connect my electrosurgical
8 analyzer go through the settings and see quantified
9 values throughout the range of that device's function.
10 So when I go back to Janice and I say Janice your
11 harmonica scalpel is all set, you know I tested it and
12 I'm going to put it back in OR 34 for you I know that
13 because of the really excellent procedure that was
14 written on that manual it is laid out step by step and
15 this device, this little dongle allows me to perfectly
16 quantify the function of that device before I return
17 it. You know this is an example of the way it should
18 be. And from my world at the workbench I want to
19 bring perfectly functioning and safe devices back to
20 my caregivers. That is my job; that is what I do.
21 MR. RIDGWAY: And to dream a little bit if
22 it was really a critical device like an MRI wouldn't

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1 it have been nice if it was built in and there was an
2 idiot light at the front of the MRI that says if this
3 light is green; it is working as it should. I don't
4 think I'll live to see that day but I think that is
5 what we should move towards.

6 Thank you.

7 MS. SCOTT: I do want to mention that we had
8 one question received online that was really focused
9 more toward again ISO regulation and so we are going
10 to save that question for later. We have documented
11 it but we are going to save it for the later
12 discussions.

13 And I did want to ask one more question that
14 we had and I think it is a good question and I'd like
15 to ask at least one representative from an OEM, one
16 representative from the hospital, end users and
17 engineers, and one representative from the ISOs to
18 give your feedback related to this question.

19 How do you approach risk mitigation and how
20 can servicers and OEMs work together to mitigate risk?

21 MR. BAIRD: Could you repeat the first
22 question because it sounds really big.

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1 MS. SCOTT: How do you approach risk
2 mitigation and I guess from an OEM's perspective how
3 in general do you approach risk mitigation if we put
4 it in the framework of this workshop in terms of
5 repair and refurbishing and risk association with this
6 whole general issue. Does that help?

7 MR. MOOREY: I'd be happy to jump in there
8 from the ISO perspective. So I'll speak from my
9 experience. We have a quality department whose job is
10 to do nothing but review the data and look at trends.
11 When we have those trends, we see alarming trends we
12 do deep dives and we develop CAPAs against those as an
13 organization to make sure we address those.

14 From a vendor side we have a whole
15 department that does nothing but quality vendor
16 analysis. They do site surveys; they do analysis of
17 them to make sure that the parts are coming in. They
18 look at the data to see if we have higher failure
19 rates; those type of things. And they are engaging
20 with our suppliers to make sure they are supplying us
21 the type of parts, the quality of parts, the
22 timeliness of parts that we need in order to support

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1 our customers.

2 And then ultimately like I said we are
3 surveyed every three years at each of our sites from a
4 regulatory perspective to assess our total program
5 effectiveness. I can tell you, all of my competitors
6 will tell you this we meet on a regular basis, if not
7 weekly, certainly on a monthly, quarterly and annual
8 basis to review our program and provide them with
9 metrics so they have the data to assess are we doing
10 what we say we do. And if we are not, then we work
11 together to create those correction plans to address
12 those.

13 DR. HEMPHILL: So I can try a little bit on
14 that one because it is a big issue. We're trying to
15 and whether it is devices or other things we're trying
16 to think you know what do high reliability
17 organizations do and in part it is measures that
18 matter and things that you can look at that are
19 supposed to be those kind of early warning systems.
20 I mean we would have said that today's problems are
21 yesterday's unmanaged risks. So yet through all the
22 noise how do you figure out what's really truly a risk

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1 that you should be trying to do. I think we would
2 look at this from a couple of different ways. In
3 terms of equipment that we have in our systems that
4 we've been using for a while we really are trying to
5 get the human intelligence system because sometimes we
6 think by the time it's an obvious trend it is actually
7 already a big issue, is to really give them easy ways
8 to say this just doesn't feel right, it doesn't seem
9 right and allow them the ability to report through
10 those systems so that we can try to do a deeper dive
11 on equipment. And so that would really be for
12 anything in the system. Are you feeling like this
13 isn't working quite right? And then if we see that --
14 and is it happening there, then could it be happening
15 everywhere. Where else do we have those pieces of
16 equipment?

17 But in terms of what we really would like to
18 think of in terms of bringing equipment into our
19 system that's where we really want to try and say to a
20 manufacturer what are you seeing in your own systems
21 already. I mean everything that you design most
22 people feel like they've made some tradeoffs in design

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1 and feature. Where do you worry about some of the
2 things that don't work quite as or where you've seen a
3 few vulnerabilities. We understand that it is very
4 difficult to make a perfect device, a perfect piece of
5 equipment. And again getting back to what I said
6 before and assuming that that piece of equipment is
7 going to seamlessly weave into what is an almost
8 infinite number of systems, people, and just sort of
9 processes. But if we know some of your areas of
10 vulnerability and if we can sort of also try limits of
11 use testing in some cases we are better prepared for
12 the things that we know aren't perfect about these
13 systems that you are designing already. And so we
14 think of this under a broad heading of purchasing for
15 safety which is how do we work with many of you to
16 figure out your systems, what you know about them,
17 what you don't know about them, test them a little bit
18 in advance but then also create those early systems to
19 get word back to you about what's working or not
20 working well for us. Easy to say, very hard to do.
21 But again you want a green light on an MRI. I would
22 never trust the light.

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1 [Laughter.]

2 I'd be like is the light working. And so it
3 still gets back to that but what you said was right.
4 I mean how can we create a better awareness of what
5 right looks like whether or not I'm bringing it in to
6 begin with or whether or not it is in that life cycle
7 of use and re-use. And that has to be kind of a
8 transparent system of this is what right looks like.
9 And this is how you would know a year from now that it
10 still is what right looks like. So that I know it is
11 going south, I can get somebody in the moment, my
12 biomedical engineer to help me figure out how it is
13 going south, bring in manufacturers to also help us
14 figure this out. But certainly for the point that we
15 are also using other companies to help us with some of
16 our refurbishing, reprocessing they need to know what
17 a right looks like as well so that we all have a
18 shared mental model of this machine is working as
19 designed.

20 MR. BEINKE: I mean I like much of what Rob
21 and Robin said. I mean especially what Rob said it
22 sounds like what we do as manufacturers. You know we

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1 have a systematic approach to evaluating the data that
2 we have and we have a feedback loop and it forces us
3 to analyze and react to that. This is a key point to
4 exactly what we're as OEMs trying to point out. If we
5 are missing segment of data then we can't
6 appropriately do that. We can't do the mitigations
7 that you ask about. So for us it is incredibly
8 important that we get all of the information so that
9 we can have that feedback loop and do the mitigations
10 as necessary.

11 MR. ANBARI: And similarly from an
12 independent service repair organization we take a true
13 enterprise approach to how we manage risk and mitigate
14 risk I should say. For us it is less about detection
15 and it is more about prevention. And it reflects the
16 way that we handle our sourcing; it reflects the way
17 that we handle our staffing and training of our
18 technicians, it reflects the way that we handle our
19 repair process with interim quality control checks and
20 the quality control technologies that we use and it
21 reflects the way frankly that we even return the
22 device back to the hospital knowing that sometimes

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1 shippers aren't the most gentle of all creatures. But
2 we really look at the risks across the entire spectrum
3 of our services and have mitigation programs that we
4 put in place that are appropriate to that very stage
5 whether it is sourcing and how we select suppliers,
6 how we ensure that materials are the same as what a
7 manufacturer used, or in many case from a sourcing
8 standpoint trying to identify the same sources that
9 were used by a manufacturer.

10 So in some cases that works. In other cases
11 it doesn't. But regardless it is about that
12 enterprise level strategy that we take from top to
13 bottom.

14 MS. IYER: I'd like to make a comment. So
15 I've had an interesting experience being on the
16 research side of medical device development and now
17 being with an OEM I work very closely with those who
18 perform the research and the engineering behind it.
19 And so sometimes when the device is very early in
20 concept you sometimes lose sight of what the ultimate
21 fate of that device will be. But we as the OEM we
22 carry that with us throughout the life cycle of that

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1 device no matter who touches that device. And during
2 this panel today I hear themes about what is the
3 intended use of the device, what are potential errors
4 and use errors, risk mitigation, risk management
5 strategies; these are all things that we have to take
6 into consideration before we can market a device.
7 There are already formal mechanisms in place. And I
8 think ultimately what we need to do is work together
9 to leverage the mechanisms we already have in place
10 keeping in mind that the ultimate goal that all of us
11 share is patient safety.

12 Thank you.

13 MS. SCOTT: And Mark.

14 MR. LEAHEY: And just a final point. And
15 again I think to touch on what Hans said is just
16 having that complete service record of knowing every
17 hand that touches the product so we can make sure that
18 it all feeds into the same quality system. And maybe
19 David you just said you are more focused on
20 prospective I guess but I think at the outset you
21 talked about a file cabinet of OEMs of poor service.
22 I just would like to ask when you have that file

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1 cabinet do you provide that information back to the
2 OEM or does the hospital report that? Has that file
3 cabinet been reported and if so, who gets that
4 information?

5 MR. ANBARI: We routinely provide when we
6 find inappropriate repairs we routinely provide those
7 photos back to our customers. And we don't always,
8 like the manufacturers we don't always know the
9 service history because customers are fickle and they
10 tend to move from service provider to service provider
11 at times. We know our history with it and we have
12 that visibility and we can certainly provide them
13 insights. But we use those images for two purposes.
14 One, we do provide it back to the customer so that to
15 the extent that they've had someone else working on
16 the equipment or working with the equipment they can
17 coach them. But more importantly the majority, the
18 overwhelming majority of the damage that we see is the
19 direct result of wear and tear or inappropriate use of
20 the device in some way whether it is in use or
21 reprocessing and we use those pictures and that
22 imagery to be able to create a story that we go back

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1 to talk to the customers about about how they can
2 avoid those kinds of problems in the future.

3 So in many ways if the information were to
4 flow back to the manufacturers it would flow back
5 through the customer as opposed to directly through us
6 at this point in time.

7 MR. LEAHEY: Great. And again I think
8 getting that totality it is important to make sure
9 that that information gets to everybody and you just
10 acknowledged that when you service it you don't even
11 know who serviced it before you which demonstrates
12 that although the hospitals may have requirements in
13 place to document all the servicing it is clearly not
14 being implemented across the board consistently right
15 now.

16 MS. SCOTT: Okay. Well, I'd like to thank
17 our panel for this afternoon. This concludes Panel 1
18 this afternoon. We are going to take a ten minute
19 break. I would like to ask for those participants who
20 registered to present for the session this afternoon
21 if you are confirmed to present for the session this
22 afternoon please come to the front at this point for

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1 additional instructions.

2 And with that again I thank our panelist and
3 we will have our ten minute break.

4 BREAK

5 MS. SCOTT: Thank you. Again for those who
6 registered to present this afternoon we ask that you
7 can go ahead and you can begin to line up at either
8 the front or the back microphone.

9 Okay. Excellent.

10 When you do come to the microphone again I
11 ask that you state your name and affiliation. We're
12 going to jump back and forth between the two
13 microphones. We will start with the front microphone.
14 Then we'll go to the back microphone. Then we'll come
15 back to the front microphone. And we'll keep
16 alternating like that. Okay.

17 PRESENTATIONS BY PARTICIPANTS

18 MR. McBRIDE: Good afternoon. My name is
19 Jeff McBride. I am the President of Red Lion Medical
20 Safety, Inc. Red Lion has been in business for 38
21 years. We are an ISO and we service anesthesia
22 machines biomedical equipment and medical gas and

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1 vacuum systems in hospitals and healthcare facilities
2 from Washington, D.C. up through New York City.

3 In the late 1990's Red Lion Medical Safety
4 was the lead plaintiff in a lawsuit against a major
5 OEM in the medical equipment field. We filed the
6 lawsuit against the OEM for restriction of trade,
7 monopolization of the service market. This case was
8 settled out of Court in 2000.

9 Here we are now 16 years later and Red Lion
10 Medical again is the lead plaintiff in another lawsuit
11 against a successor OEM for restriction of trade,
12 monopolization of the market; some of the same exact
13 plaintiffs, some of the same exact arguments, some of
14 the same exact problems against essentially the same
15 exact OEM. We did not want to have to file this
16 lawsuit but they gave us no choice. It seems very
17 clear that the OEM is using this as a bully pulpit to
18 force the competition out of business.

19 By not supporting the ISOs the OEMs can
20 create the appearance that the ISOs are not trained
21 properly, that we do not have the technical expertise
22 to service the medical equipment and that we cannot

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1 obtain parts. This stance by some OEMs can as one
2 writer put it cause patient harm indirectly by not
3 providing the parts in a timely manner some equipment
4 goes months without repairs. Some ISOs are being
5 charged a flat rate of \$1000 for an overnight shipment
6 of parts. Currently for a one week training class by
7 a manufacturer it is in excess of \$15,000 for one
8 machine. To put that in perspective my son is
9 currently going to a university and is working on his
10 Bachelors degree. For two semesters, 32 weeks, it
11 costs approximately \$12,000; \$3,000 less than what it
12 costs to take this one week training class.

13 Some of the manufacturers will provide
14 access to training classes only on a limited basis;
15 they will provide a class just for ISOs. If there are
16 not enough ISOs registered for the class they will
17 cancel this class. By using these tactics they can
18 force ISOs into losing service contracts because we do
19 not have proper training.

20 There are some OEMs that charge for dial-in
21 tech support. Before you can even start a technical
22 conversation you have to provide them with a credit

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1 card. The cost for this can be \$675 per hour and it
2 is based on 15 minute increments.

3 These increased costs have to be passed on
4 to the customers who eventually pass them on to the
5 patients. During the time that Red Lion has been in
6 business we have not had any major incidents that have
7 caused patient harm. Red Lion ensures that our
8 technicians are factory trained and we only use OEM
9 parts.

10 I have read several reports from the
11 manufacturers and their leading associations. I noted
12 that they identify numerous instances that third party
13 companies or ISOs have improperly repaired equipment.
14 However, I did not see one instance reported that the
15 OEM made a mistake. Do they not make mistakes as
16 well?

17 In closing even though the ISOs have to pay
18 a higher cost for training, parts, shipping, and
19 technical support, we can still provide a better
20 customer service and at a cheaper price. If the FDA
21 is truly concerned about patient safety and the
22 increased costs of health care I would recommend that

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1 they take a closer look at how the manufacturers
2 impact and support the Independent Service
3 Organizations and third party service providers.

4 Thank you.

5 DR. HEMPHILL: Robin Hemphill again from the
6 Veterans Health Administration. I am struck a little
7 bit by a lot of things that are coming out of this
8 discussion. And I try to have that inform comments
9 about how we are trying to approach things. It is
10 striking to me that at the beginning of my career, I
11 would have said I came to work with a pen and that
12 felt like it was about all I needed, along with a
13 scalpel. And I don't think I am dating myself
14 entirely by sounding like a dinosaur because how
15 things have changed has been almost explosive.

16 So as we look at the thing that we begin to
17 try and track and trend certainly the interaction of
18 devices as they come into our system, and I mean
19 really all devices, and I would also throw in there
20 the sense of medical IT, same type of thing, its
21 interface with people, end users as us, our patients
22 and then the other environment around it is really an

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1 area of enormous growth for us. And we are still
2 trying to get our arms around it. So when I say what
3 keeps me awake at night it is very much this exploding
4 world of fascinating technology and the double-edged
5 sword that it really is for us; all of the promise
6 but, of course, much of the peril.

7 So we are trying very, very hard to get arms
8 around it and understand it and so again that gets
9 back to the reporting systems and the importance of
10 them. Providers today still struggle greatly with the
11 sense that we contribute to medical harm. And we
12 still as providers are often in a lot of denial about
13 that. And yet more and more data comes out and we
14 still often deny, deny, deny; we don't have a problem.

15 So I feel like we are going through the five
16 stages of death and dying; making our way finally to
17 acceptance. We have a lot of errors that we make and
18 so I would encourage again this group across both the
19 front-end OEM as well as the providers and those who
20 use it and then those who try to fix it and keep it up
21 I think the absence of data is not an absence of a
22 problem. I think we are still widely underestimating

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1 that. So we are trying to collect that information as
2 much as we can and understand when is it the device,
3 when is it the provider, when is it a mix.

4 We are also committed to in the next couple
5 of months to try and understand across our enterprise
6 what is the history of devices and how they are being
7 reused so that we can get to that sense of when is
8 even the way we try to reprocess or refurbish or fix
9 up when is that contributing to some of the harms. We
10 hope to be working with the FDA in trying to create
11 those systems of reporting.

12 But again as frightening as that can be to
13 report our problems both when you bring something in
14 and they are brand new as well as when they are
15 getting used throughout the life cycle, as frightening
16 as that is we can't fix what we don't know about.
17 We're going to try and commit as an enterprise in the
18 system from the VA to understand and report to FDA as
19 wonderful partners for us and to manufacturers when we
20 can; and we will try and expand that knowledge into
21 how we're reusing, reprocessing; so in other words,
22 that life cycle in between that cycle and get that

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1 information and make it as transparent as we can as
2 well. But certainly we need partners who are willing
3 to hear those messages.

4 Thank you.

5 MR. BRULEY: Thank you. And good afternoon.
6 I'm Mark Bruley, Vice President for Accident and
7 Forensic Investigation at ECRI Institute.

8 FDA's proposed rule request for comment
9 seeks to aid them in exploring the issues of medical
10 devices that are subjected to post market activities
11 performed by original equipment manufacturers and
12 third parties including the hospitals themselves.

13 ECRI Institute's response focused on FDA's
14 question number two on evaluation of risk with these
15 third party and OEM activities. And to paraphrase
16 that question asked what evidence exists regarding
17 actual problems with safety and/or performance of
18 devices from activities of refurbishing, servicing, et
19 cetera. Specific examples should be submitted.

20 Let us begin with the tenant that specific
21 examples and anecdotes are not data. Regulation that
22 affects the safety and cost-effectiveness of the

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1 application of medical technology to patient care must
2 not be entered into without evidence of a problem that
3 needs to be remediated.

4 So let's look at the data both from the 1997
5 FDA regulatory initiative on this topic and for the
6 past ten years. ECRI Institute has nearly five
7 decades of experience monitoring problems with hazards
8 of medical devices and is well qualified to speak to
9 the issues of what evidence exists.

10 To answer the question on evaluation of risk
11 we conducted extensive searches spanning ten years
12 from 2006 to 2015 of FDA's MAUDE database, ECRI
13 Institute's Health Devices Alerts Tracker Recall
14 database, National Library of Medicine PubMed database
15 and ECRI Institute's confidential contracted
16 investigations of medical device incidents that have
17 caused serious injury and death. We used extensive
18 key word and text string search strategies to identify
19 records that describe problems with capital medical
20 equipment related to refurbishing, reconditioning,
21 rebuilding, et cetera. We omitted from the analysis
22 reports on prostheses, implants, reagents, and

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1 disposable devices. Our search strategy of
2 denominators for the data are in our comments
3 submitted to the FDA. The current search strategies
4 are similar to those performed in 1998 that I
5 presented at an FDA AAMI conference about the 1997
6 proposed regulations.

7 At the 1998 conference I presented the data
8 from our analysis from FDA's then 18 year old device
9 experience network and at that time the two year old
10 MAUDE database. More than 750,000 records were
11 searched; approximately 137,000 which is 19% of these
12 were related to capital equipment. Of those reports
13 for capital equipment spanning 20.5 years 241 relevant
14 reports were found representing 0.17 of those capital
15 equipment reports. There was no evidence that a
16 safety problem existed that needed to be addressed by
17 regulatory action.

18 FDA at that conference was then asked what
19 it found in their analysis. They too said they could
20 find no evidence that a safety problem existed. That
21 is in 1998.

22 In the current ten year analysis we searched

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1 more than 3,600,000 records of combined MAUDE health
2 devices alerts and ECRI Institutes Accident
3 Investigation case files. There was nothing in
4 PubMed. Of those more than 2,115,000 related to
5 capital equipment. Based on searching for possible
6 relevance thousands of reports were then read. We
7 found a total of 96 relevant reports out of the
8 2,115,000 records. That is an incidence of as
9 mentioned before 0.005%.

10 That incidence related to the theme of this
11 workshop is now two orders of magnitude smaller than
12 what was found in 1998. Based on the results of ECRI
13 Institutes detailed searches spanning the past ten
14 years and on our monitoring of medical device problems
15 for more than 40 years we do not believe that a safety
16 problem exists with refurbishment, remanufacturing,
17 servicing, maintenance and repair of medical devices
18 by either third parties or OEMs.

19 We see no valid argument for an FDA
20 regulatory initiative on the premise that there is a
21 history of safety or performance problems that are
22 compromising patient safety.

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1 Thank you.

2 MR. SCHNEIDER: Hi, Rich Schneider from
3 TriMedx.

4 I wanted to spend my five minutes really
5 reemphasizing some of the key benefits and address
6 some risks that we've heard today.

7 The first one is really around
8 responsiveness. ISOs like TriMedx or in-house
9 clinical engineering programs really act as an arm of
10 the hospital of our customer. We don't go around
11 wearing TriMedx badge, logos on our shirts; we are
12 seen as partners and part of the hospital. What that
13 allows us to do by being co-located within the
14 hospital is really improve responsiveness. So when a
15 mission critical device is hard down because we are
16 there we can get that device back up and running
17 within hours. Most of them are done within four
18 hours, within 24 hours over 95% of hard down mission
19 critical devices are back up and running. That
20 addresses really provider satisfaction but most
21 importantly patient safety. So that is a key benefit
22 that ISOs provide to our customers.

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1 From a cost perspective, we heard a lot
2 about cost savings as well. And we can't minimize
3 that. A lot of hospitals have financial difficulty
4 and they need these cost savings in order to provide a
5 service to their patients, an effective service to
6 their patients.

7 From a risk perspective obviously mitigating
8 risk is key. And at TriMedx, I think you've heard
9 this a couple of times today, we put in place quality
10 management program where we have an internal audit
11 team that goes out to each of our hospital sites and
12 reviews the processes and documentations that our
13 engineers go through.

14 We also have a supplier quality program
15 where we are going out and visiting our partners who
16 provide us parts and do third party repairs for us to
17 ensure that we are providing that quality necessary.

18 Why are we doing this? Obviously patient
19 care, patient safety is number one. Number two is if
20 we didn't do it we'd be out of business. So it is
21 important for us to do it from a pure business
22 perspective.

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1 And third I think you heard this earlier and
2 I really want to emphasize this is that we are
3 regulated. We are regulated, maybe not directly, but
4 through our customer, through the hospital. Hospitals
5 are regulated by the CMS, we've got Joint Commission
6 auditors coming in, we've got state health regulators
7 coming in. If we don't provide that service, if we
8 don't document our repairs and preventive maintenance
9 properly and on time those hospitals will be seen at
10 fault, we'll be seen at fault. And they'll either be
11 fined or put out of business and we can't let that
12 happen.

13 So to me we don't need that additional
14 regulation by the FDA. What we need is the walls to
15 be knocked down between the hospitals, the ISOs, the
16 in-house clinical engineering programs and the OEMs.
17 At TriMedx we have some great OEM partnerships. Some
18 other OEMs really don't want to work with us. And we
19 need the training, we need the access to parts to
20 really provide service to the hospitals and improve
21 patient safety and care.

22 Thank you.

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1 MR. LERSCH: Good afternoon. My name is
2 Jeff Lersch. I'm the Vice President of sales at Karl
3 Storz Endoscopy America. Karl Storz for those who do
4 not know is a worldwide leader in the production and
5 sale of medical instruments and devices including a
6 broad range of reusable rigid and flexible endoscopes,
7 instruments, camera systems and other accessory
8 devices used by healthcare providers to conduct
9 minimally invasive medical procedures.

10 On behalf of Karl Storz I'd like to thank
11 the FDA for hosting this public workshop to gather
12 insight on this critically important patient issue.

13 During my brief comments this afternoon I
14 will provide Karl Storz' perspective on the benefits
15 and risks associated with the five R's as I refer to
16 them in a regulated versus unregulated environment.

17 In the current unregulated environment of
18 device repair Karl Storz believes for specific
19 categories of products the risk to patients outweigh
20 the benefits being realized by other stakeholders. In
21 our filing to the docket we surfaced evidence that
22 substantiates what can happen when a patient critical

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1 or semi-critical device is repaired by a third party
2 in unregulated environment. Patient critical devices
3 can be defined as a device which comes in contact with
4 blood or sterile tissue including mucous membranes.
5 Patient semi-critical devices work hand in hand with
6 and are necessary for patient critical devices to
7 perform a medical procedure.

8 The common thread in each of the examples we
9 surfaced in our submission was that somebody other
10 than Karl Storz opened and actually repaired the
11 device compromising its integrity. And lastly in each
12 of the instances we surfaced there was an adverse
13 patient outcome.

14 Two examples in particular further amplify
15 the need to change the status quo. In the first which
16 was included in our submission material from the outer
17 sheath of an endoscope flaked off inside a patient and
18 an investigation concluded that the insulation cover
19 material was different from the material Karl Storz
20 uses in its manufacturing and repair processes. The
21 hospital that sent the device to Karl Storz confirmed
22 that it had used a third party repair company to

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1 service the device.

2 More recently we received a flexible
3 endoscope that had been repaired by a third party.
4 Our investigation revealed that a chewing gum like
5 substance, no kidding, had been used to repair the
6 shaft where it connects to the handle.

7 Both of these examples demonstrate why
8 standards for repairing medical devices must be
9 established and that regulatory oversight is required
10 to drive accountability.

11 Another concern is a lack of labeling. ISOs
12 currently are not required to clearly label devices
13 they modify leaving users with a false perception that
14 a device adheres to OEM and for that matter applicable
15 FDA standards. As mentioned third parties are not
16 required to document or report their 5 R activities so
17 there is no mechanism for any stakeholder to know who
18 has repaired a device, what modifications were made to
19 the device and how the device performs versus original
20 OEM specifications.

21 This begs the question how is this lack of
22 information in the best interest of patient safety.

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1 Conversely OEMs are required to document and
2 report all activities associated with their devices
3 establishing standards and initiating regulatory
4 oversight for all parties will level the playing
5 field, drive accountability and have a positive impact
6 on patient care.

7 Karl Storz strongly believes the FDA can, in
8 fact, develop and implement a regulatory framework
9 that protects the proprietary interests of OEMs,
10 preserves a vibrant third party repair marketplace,
11 and above all else protect patient safety.

12 DR. BITTLEMAN: Thank you Jeff. Sorry, we
13 have to move on. That was your five minutes. Thank
14 you.

15 MR. FRANCOEUR: Thank you. My name is Dave
16 Francoeur. I've been in the healthcare profession for
17 greater than 30 years. I've worked in every facet of
18 this industry possible, insurance, OEM, in-house,
19 third party, done it all. I've had thousands of
20 technicians that reported to me through the career.
21 I've had millions of work orders that have been
22 processed under my indirect or direct responsibility,

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1 a lot of which was responsibility for the quality.

2 I want to first start out by saying we have
3 to understand the way I work on things it is around
4 understanding the why. So why are we here? And my
5 perspective I feel that we are here because we are
6 focused on patient safety. Well if we are truly
7 focused on patient safety then we are going to have to
8 break down the walls because whether we want to admit
9 it or not cost and competitiveness are definitely two
10 factors that are causing the problem for the reason
11 why we are sitting here today.

12 Second thing that's an issue that I think we
13 need to address is we're here because we are either
14 going to ensure increased or improved patient safety.
15 Well obviously we don't know which of those it is
16 because again if we did I don't think we'd be sitting
17 here today. So the fact of the matter is I think we
18 have to decide what it is that we are trying to
19 achieve and how we are going to do that. And the only
20 way it is going to happen is if we break the walls
21 down between the OEMs and non-OEMs because really
22 whether you are in-house or ISO doesn't really matter

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1 because you are not OEM. And as I said I've worked
2 for OEMs in the past.

3 Next think I want to say is that I've
4 changed my view a little bit just since I've been here
5 today and over the day. I think there may be some
6 merit to some sort of validation which shows and
7 demonstrates there's somebody that is working on a
8 piece of equipment that has some level of criteria and
9 the ability to make sure that they can work on those
10 pieces of equipment. I don't disagree with that. But
11 the fact of the matter is the challenge we are going
12 to have is how are we going to measure that. And how
13 are we going to monitor that.

14 Next thing I'll say is that if you are going
15 to go down that road then we have to make sure it is
16 on both sides because I do believe regardless of
17 whether your paycheck comes from OEM or comes from In-
18 house or comes from ISO or comes from wherever it
19 comes from, whether your training comes from an ISO or
20 independent third party group or someplace else the
21 fact of the matter is the skill and the level that the
22 person who sits in front of that piece of equipment is

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1 only as good as that person that is there at that
2 time. And I can demonstrate time and time again it
3 doesn't matter again where your paycheck comes from or
4 where your training comes from because if you are
5 going to circumvent the system, if you are not going
6 to do it because you're not the type of person that is
7 going to do it in the first place it is really not
8 going to matter where your training came from or your
9 paycheck comes from.

10 So with that I would just say that the
11 benefits would be if we all did come together and we
12 truly did do what we're professing we say we want to
13 do in this room which is to increase patient safety
14 then lets break down the walls and make that happen.

15 But the challenges are going to be to figure
16 out how we are going to do that because we don't have
17 the tools that we need, we're not willing to share the
18 information back and forth, and so much as the OEMs
19 have told us on numerous occasions if they had the
20 data they could make decision, well then let's do it
21 the other way, give us the data and let us help you
22 make the decisions.

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1 So all I'm saying is we can sit here and
2 banter this forever; it is never going to change
3 unless we decide to change it. So I'll just throw
4 that out there. With that that is my perspective and
5 I appreciate your time.

6 MR. GREEN: My name is Thomas Green. And
7 I'm the President and Owner of Paragon Service located
8 in Michigan. My company services, we're an ISO.
9 Actually we were the very first anesthesia ISO in the
10 country. We were the second anesthesia refurbisher in
11 the country. We are also distributor of anesthesia
12 equipment.

13 And I wanted to get up and speak because
14 I've heard some things I really don't like hearing
15 right now. And I wasn't going to speak but I'm going
16 to.

17 There are some things bantered around that
18 are gray areas. You want to hear facts well first of
19 all I'm going to speak on behalf of Thomas Green of
20 Paragon Service. Tomorrow I'm on a panel. I'm going
21 to be representing ISOs but I want to speak on my
22 behalf today.

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1 I have been in the anesthesia equipment
2 business for over 35 years and 26 years ago I started
3 Paragon Service. You want to talk about critical
4 equipment, anesthesia equipment. It doesn't work,
5 people die. You want to hear facts, 15 to 20,000
6 service procedures have been performed by my little
7 company; we've sold between two and three thousand
8 refurbished anesthesia machines, thousands of patient
9 monitors; no returns. No adverse events. No patient
10 harm.

11 You want to hear stats. No patient harm.
12 And yet we have to stand here today and hear that ISOs
13 and refurbishers are unsafe. Mark can talk about his
14 statistics of five thousands of a percent including
15 OEMs.

16 Here is an example of a company that has no
17 patient harm. Yet we are here today. This is crazy.
18 Needing further regulation; MITA just wants this to
19 put us out of business and increase their costs
20 period.

21 ISOs are safe, fast responding and can do it
22 forty to fifty percent less than OEMs. They don't

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1 like us. Further FDA regulation will not improve the
2 statistics of Paragon Service. 26 years from now we
3 are still going to have no patient harm and we don't
4 need the FDA to regulate us.

5 Thank you.

6 MS. WILLIAMS: That is going to be hard to
7 follow.

8 [Laughter]

9 Good afternoon. My name is Nicole Williams.
10 I'm a microbiologist and Vice President of Medical
11 Optics. We are a third party repair company out of
12 Tamarac, Florida.

13 I've actually been doing this for over 16
14 years. I know it doesn't look it by my young exterior
15 and so I've also worked for the OEMs and ISO so I see
16 this from both points of view.

17 It is as the day has gone by today I had a
18 little speech prepared but it is very hostile and I
19 think this subject is always going to be a hostile
20 thing. And it doesn't have to be. I've been actually
21 disavowed by my previous OEM. They are like we'll at
22 least pretend she doesn't work there anymore which

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1 why? I have that knowledge; it doesn't go away just
2 because I don't work there anymore. I am a
3 microbiologist; I'm all about effects control and
4 patient safety. And that is what is important. And
5 that is what everyone is forgetting with the fighting
6 that has been going on today.

7 What is important is that there are very,
8 very good companies here that do very, very good work.
9 And there are companies that do very, very bad work.
10 There are people that replace stuff with bubble gum in
11 their garage. And there are people like my company
12 who are ISO certified by both 9001 and 13485 that do
13 material compatibility on every part that touches a
14 patient, every part. And I will gladly show anyone
15 the test report for that because I make sure it
16 happens, because that is important.

17 We do reprocessing testing on everything.
18 We also have huge complaint procedures just like you
19 are required to if you are ISO regulated. If they
20 come in and check you then you have to have everything
21 that you do. I don't know why this is a surprise to
22 everyone here and why we are having a battle. It

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1 needs to be fixed. It is important. It is money. I
2 don't care what anybody says, it is. All you have to
3 do is cooperate. If Olympus would like to have our
4 repair data, I will happily give it to them. I have a
5 lovely online program where my customers can log in
6 and see it. This is not a surprise.

7 We do this, third parties care about their
8 patients. We are more fit to represent our hospitals
9 than some OEMs. We do better training. One OEM in
10 this room I went to do training with their supposed
11 clinicals and they made me do their clinical training
12 because they didn't know the product. It is very
13 important. Customers need training. They need those
14 special things that the ISOs give them that the OEMs
15 do not. You have other things to worry about; let us
16 worry about the customer service.

17 And honestly we can rehash the same thing
18 over and over again but I feel like this is what we
19 are going to talk about for two days and not get
20 anything done.

21 Maybe you need an Italian up there and we'll
22 just take a vote and figure it out. Now my boss is

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1 going to be mad at me because it is nothing I wrote
2 down and made him read today.

3 [Laughter]

4 Sorry, Frank, because I know you are
5 watching me right now.

6 So in closing since I've said nothing that I
7 was supposed to say in the first place, I think that
8 we can make this work. We don't need to have FDA
9 regulations if everyone has their 13485, everyone does
10 what they are supposed to do and we all share a little
11 bit of information. There is enough business to go
12 around for everyone and it is for the betterment of
13 the hospital.

14 Thank you.

15 MR. BEINKE: I'm Hans Beinke with Siemens
16 Healthcare. I don't have anything too formal
17 prepared. Just a couple of notes that I took as we
18 went through the session today.

19 First thing I thank FDA for organizing this.
20 I think it is valuable. One of the speakers just said
21 that he's modified his thinking by some of the
22 comments here. I've certainly learned some things.

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1 So I want to thank everybody that's provided comments.

2 Again as has already been said I think Mark
3 Leahey said it first there is a lot of agreement in
4 this room. And I think that is what we need to focus
5 on. I think there is a lot of detail that we need to
6 get to and there is some work to get there. I think
7 FDA has a lot to consider.

8 We've said it and I'll say it again this is
9 not about trying to put ISOs out of business. I
10 suspect that most, if not everyone in this room, there
11 is not an issue. I think it is others that we need to
12 be concerned about. And that is true for OEMs as
13 well. We have good players, we have bad players. We
14 have regulations to keep up with what they do.

15 So I don't hate ISOs.

16 To reiterate what we've said, what we do
17 believe as OEMs is that you should have a quality
18 system and again many people in this room have a
19 documented quality system. So I think for those
20 people that is covered.

21 I think one of the areas I do worry about is
22 the reporting. We need that reporting so that we can

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1 do trending. And I think we need to have better
2 communication in that area.

3 I do think that we have a need for
4 regulatory oversight. I think patients and again this
5 is not something that hasn't already been said
6 patients should be able to assume that there is no
7 difference, they walk into the hospital, they are
8 treated and they don't have to sit there and worry
9 about who did the service. And again I think that
10 there are many, many good players.

11 We need to protect ourselves; ISOs, OEMs,
12 industry in general by making sure that we are
13 constantly driving quality.

14 We talked about anecdotal information. I
15 think there is some truth to that because we don't
16 have access to all of the information but I will
17 remind you for the person that it is anecdotal it's
18 important for that individual. We can't dismiss
19 everything as anecdotal. There are people behind
20 this.

21 Also there has been a lot of talk about
22 event reporting, harm, death; we need more than just

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1 that. We need again to be able to do the trending.

2 Now, I'll mention just some statements that
3 have been made that I either want to comment on or
4 have some resistance to.

5 The statement has been made a couple of
6 times that this person used to work for an OEM. I
7 think there may be some help there but I don't think
8 that is the end of it. Our OEM service providers are
9 trained and trained and trained again. We have new
10 products. Those new products require new training.
11 So great that there are some prior OEMs in ISOs and
12 hospitals; it is not the end of the process.

13 Only a few problems. I don't see us
14 regulating OEMs or I don't think that the ISOs or the
15 hospitals should be regulated by some belief criteria
16 that the level is too low to regulate. I mean if that
17 were the case then maybe we should all have a
18 submittal to FDA and if we were below a certain
19 criteria, we are off the hook, we are not regulated.
20 What about tomorrow?

21 There was a presentation or mention at least
22 that there is going to be some tomorrow about

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1 standards. I am a fan of standards. We've worked
2 within MITA to develop some standards. But a standard
3 on the shelf doesn't do much. What is the oversight
4 to see that it has been implemented and that it has
5 been implemented properly?

6 Also there were some statements that said
7 our organization is committed to quality. I've never
8 heard an organization say they are not committed to
9 quality. Quality is number one. Oh, well, for our
10 organization it is number two. Okay.

11 The other thing and I said it earlier up
12 here what is regulation? Don't have a knee jerk
13 reaction and say it is terrible. I think we have work
14 to do to decide how much makes sense.

15 And finally a steal from Mark Leahey again
16 trust is great but verify.

17 Thank you.

18 MS. SCOTT: Are there any others from the
19 people who actually registered to present who have not
20 yet come to the microphone?

21 Okay. If not, we can move on. I think
22 there was at least Scot Mackeil wanted to present this

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1 afternoon, he has a few more words he'd like to share,
2 so go ahead Scot.

3 If there are any others from the audience
4 who would like to share, again, you would only have
5 five minutes to share a perspective if you would like
6 to, you may come to one of the two microphones.

7 MR. MACKEIL: My name is Scot Mackeil and
8 I'm a Senior Biomed at Mass General Hospital. And I
9 am a quality system.

10 We spoke today of benefits and risk. In my
11 36 year biomed career I worked in many roles. I work
12 in the OR at a thousand bed academic medical center.
13 I worked 19 years in a financially disadvantaged
14 community hospital. I worked ten years as a clinical
15 lab equipment specialist and refurbisher for regional
16 ISOs and equipment remarketers.

17 From my workbench I have seen many benefits
18 and risks as technology and economics are connected to
19 patient care and safety. In years past the level of
20 corroboration between biomed and manufacturers in our
21 industry was much better. Today it is increasingly
22 difficult as collaboration is in short supply.

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1 The words liability and proprietary are used
2 to build walls between manufacturers and servicers.
3 When discussing benefits and risks let's focus on
4 patient safety, caregivers, healthcare systems and
5 leave the wall building out of our conversation. And
6 the cause of patient safety and equitable and
7 affordable care we can all be stronger together.

8 It is common for biomed to be called to the
9 point of care to resolve emergent technology problems.
10 Biomed are often able to respond immediately,
11 mitigate risk and solve problems with little delay.

12 In scenario A biomed is empowered by the
13 manufacturers. He studied the comprehensive factory
14 service manual, had training, can access diagnostics,
15 has parts, the issue is quickly resolved, care is
16 resumed, risk to the patient is minimized.

17 Biomed B in scenario B is denied access to
18 these resources, the device's role, the treatment is
19 essential yet the biomed must say I'm sorry doctor I
20 think it is broken; we have to take it out of service.
21 I'll call the company, we might be able to get them
22 here early next week or I'll have to get this boxed up

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1 and send it to the factory. I'll see if I can get a
2 loaner and I'll get this fixed as soon as I can.

3 In Scenario B the doctor must stop, modify
4 or limit the procedure and the patient's care is
5 impacted. Risk factors multiply. The patient may not
6 have received the treatment they needed or the case
7 may need to be rescheduled. Other cases that depend
8 on this device must be modified, cancelled or
9 rebooked. Schedules and care of many patients and
10 caregivers are impacted as the ripples of the failure
11 spread out.

12 The manufacturer provides service for the
13 device by generating service revenue. The hospital
14 experiences risk to patient care and safety and
15 downtown while the device was out of service.

16 Which scenario does the FDA see as being
17 more beneficial for the patient? Can the FDA see
18 changing its regulatory framework so that biomed A
19 scenario is tomorrow's standard?

20 Today I'm asking the FDA not to impose
21 regulations that would limit or restrict a biomed's
22 ability or choices in servicing the needs of my

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1 caregivers. I'm asking the FDA along with medical
2 equipment manufacturers to empower biomed and
3 clinical engineers who are your customers, your
4 colleagues and allies. I would also ask for
5 recognition of the value brought to the industry by
6 our trusted third party service providers and similar
7 stakeholders. Delivering safe affordable equitable
8 healthcare with less risk benefits all of us and is
9 tied to a simple equation. Healthcare dollars do the
10 most good when they are spent directly on care.

11 To the FDA from my perspective at the
12 workbench I must have ability, choices of third party
13 services and collaborative relationships with
14 manufacturers to safely serve the needs of caregivers.
15 The combination of manufacturer's reps like my buddy
16 Dave Young from Philips and our industry's third party
17 ISOs and vendors is essential to me because it allows
18 me to present the best options to safely and
19 affordably meet the needs of my caregivers.

20 Moving forward I would ask the FDA for at
21 least this: Please settle the issues around service
22 manuals in the industry, define what must be in them,

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1 adopt industry standards for service manuals content
2 and preventative maintenance procedures and require
3 that service manuals along with access code software
4 and repair parts be available to biomedics without
5 question.

6 Lastly I speak to the FDA as my regulatory
7 partner and to manufacturers as your customer, I need
8 both of you on my team when I am at the bedside or on
9 the workbench. You are both valued partners that can
10 contribute to patient safety and affordable equitable
11 care by empowering biomedics with knowledge and support
12 as we serve our clinicians with a shared goal.

13 This is from Jeff Cooper, the founder of my
14 department, and this is what we should be doing: To
15 provide outstanding innovative technology services,
16 solutions and systems for excellence in patient care
17 and to ensure that technology never harms a patient.

18 Thank you very much.

19 MS. HORN: Hi everybody. My name is Heidi
20 Horn. I'm the Vice President of Clinical Engineering
21 Service at SSM Health. SSM Health is a non-profit
22 Catholic health system based out of Saint Louis. We

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1 have about 21 hospitals now, actually a couple more as
2 of today. And we are providing, my clinical
3 engineering service department has about 110 clinical
4 engineers, biomed and imaging technicians who provide
5 obviously clinical equipment maintenance and
6 management services to all of our hospitals system
7 wide. I've been in this business for about 18 years.

8 So a couple of things that I wanted to bring
9 up that I know other people have brought up but I
10 wanted to make sure that it was kind of clear and said
11 in the context of a healthcare provider to the FDA.
12 First of all just kind of a show of hands, just
13 curious, how many people in here by show of hands is
14 actually employed by a health system or a hospital.
15 Okay. So not a lot.

16 So we come from a little bit of a different
17 context here and I wanted again to make sure that was
18 clear and actually official docket here. So from a
19 hospital perspective there is nothing more important
20 obviously than patient care. Our sole business is to
21 care for patients, make sure that they are taken care
22 of and that they leave the facilities in better

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1 condition than when they entered facilities. This
2 goes into play also from the clinical equipment
3 standpoint.

4 So when patients are injured unfortunately
5 by a medical device end user whether it is a
6 malfunction of the device, a service issue by anyone,
7 the hospital themselves are actually directly
8 responsible for that. The hospitals are the ones that
9 are accountable I should say. The hospitals are
10 accountable for that.

11 And so, therefore, we must be the ones who
12 are making sure that the vendors whether they are
13 OEMs, ISOs or our own folks are doing what they need
14 to be doing. There is no other, well, I shouldn't say
15 no other, but health systems in general are more
16 regulated than any other industry out there. We have
17 I can tell you SSM in particular we have the FDA
18 coming in on a regular basis at one of our hospitals.
19 We have CMS coming in. We have Joint Commission
20 coming in. We have the State. We have CAP.

21 People are coming in and making sure that we
22 are doing what we say we're going to do and are making

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1 sure that we have that documentation. Somebody else
2 was talking about having documentation from the ISOs;
3 we as an in-house organization and as a hospital are
4 required to keep all the documentation whoever
5 provides that maintenance service. So if it is in-
6 house we have to provide it but we also have to have
7 it available if the OEM provides and we have to have
8 it available if an ISO provides it. So from a
9 documentation standpoint it is the hospitals again
10 that are accountable for this.

11 My point to all of this is that I mention
12 that we are one of the most regulated industries out
13 there. We self regulate because of that. If an ISO
14 or a vendor or a OEM or whatever we are going to call
15 them or an in-house person for that matter, if one of
16 our technicians is not doing what they are supposed to
17 be doing because we are accountable for that, because
18 we are liable for that we are going to dismiss them;
19 we are going to no longer do business with them. And
20 I've done this quite often, I've had to fire ISOs and
21 OEMs and vendors who have not done what they are
22 supposed to be doing.

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1 So ultimately what I would like to relay to
2 the FDA and make sure that you do understand is that
3 we are self-regulating. And we are regulated as a
4 healthcare organization. So it is very important to
5 point that out.

6 One other piece I just kind of want to touch
7 on, you know, and I won't go into it too much because
8 I notice they are giving me the five minute warning
9 here but in my health system we have 85,000 devices
10 that we manage. This past year I budgeted \$30
11 million, \$30 million to maintain that equipment. That
12 was almost double from what it was ten years ago. So,
13 when we talk about having access to parts, having
14 access to training, having access to service manuals,
15 technical support, affordability is also
16 accessibility. And having to pay \$30 million which by
17 the way I am not even sure my whole health system is
18 going to make that much this year as a non-profit, so
19 having to pay that sort of thing is not making it
20 accessible. And so again it is something that we as
21 an industry as a whole and I am including everybody in
22 this room really has to come back together and talk

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1 about because we cannot keep seeing these costs
2 skyrocket like they are and expect us to be able to
3 get the training we need, the parts we need, the
4 support we need and do a good job for the benefit of
5 the patient.

6 So that is all I want to say. Thank you.

7 DR. DOMINITZ: Hello. I want to thank the
8 FDA for this opportunity. My name is Jason Dominitz.
9 I am a gastroenterologist. I think I am one of the
10 few end users here at this meeting who is actually
11 handling these devices and putting them into patients
12 or dealing with them directly with patients.

13 I'm the National Director for
14 Gastroenterology for the Department of Veterans
15 Affairs. I'm speaking as an individual today. My
16 comments may or may not be those relevant to the
17 official policy of the VA.

18 When it comes to endoscopy there is over 14
19 million colonoscopies done every year, there is over
20 500,000 ERCPs done a year. In the VA we do about
21 400,000 GI procedures a year. So 500,000 ERCPs done a
22 year in the U.S. and many of you may be familiar with

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1 the horrible situation we had in the last couple of
2 years with the duodenoscopes; the superbug infections
3 as they were known, the Carbapenem-Resistant
4 Enterococcus, so 500,000 procedures but we didn't
5 discover that there was a problem with these
6 endoscopes that have been in use for many years until
7 these rare infections turned up and those were largely
8 discovered by luck. It was almost entirely by luck.
9 So I think you have to think about that when you talk
10 about the low rates of problems being discovered.

11 I helped write infection control guidelines
12 for endoscopes and we talked about how the risk of
13 infection was less than one in a million; we were all
14 very convinced that the risk of problems was
15 incredibly low but we just didn't have the right data.
16 So I am very concerned as Dr. Hemphill said earlier
17 the lack of data is not the same as the lack of a
18 problem.

19 So I think we need better data. We
20 shouldn't bury our heads in the sand. We have near
21 misses. As a gastroenterologist we have problems when
22 the endoscope doesn't work like it is supposed to, the

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1 wheels don't turn quite right, we've had lenses or the
2 cameras mounted upside down, we've had cables mounted
3 improperly, improper angulation. I don't know if it
4 is ISOs or the OEM doing these repairs. I don't
5 really care. I just want to make sure it works. And
6 it doesn't always work right. And it is not going to
7 result in serious harm but it could delay the care.
8 We may have to switch out to another scope which, of
9 course, increases the cost.

10 So I think we need better reporting systems
11 for when we have these problems. How do we synthesize
12 this data? You know it is not being synthesized right
13 now. I don't know if the third party vendors are
14 doing, the OEM are doing the repairs, maybe they need
15 service bulletins to say that this scope had this kind
16 of problem, you need to trend that data. So I do
17 think we need better training, availability of parts
18 and manuals to make sure that our patients are getting
19 high quality equipment being used in the hands of the
20 physicians.

21 Thank you again for this opportunity.

22 SPEAKER: Hi, my name is Cory. I'm from an

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1 OEM manufacturer of dental, mostly dental chemicals
2 like composites and things. We have a couple of piece
3 of hand held equipment.

4 I am not speaking in my company's capacity.

5 I am regulatory affairs manager. I would like to
6 point out to FDA that not all equipment has the same
7 risks; not all equipment is installed; not all
8 equipment is used in hospitals; not all of it is
9 serviced in the field. We do not have any field
10 service engineers, all of ours are very small; they
11 are sent back to us. We repair them; they are not
12 used in high risk types of procedures.

13 So a final regulation should also be sure to
14 cover devices like these, you know, scalable to small
15 specialty, low-risk, non-installed devices that are
16 serviced by the OEM. Most of the parts are specialty
17 parts. You can't buy them off the shelf.

18 So I just want to be careful that the final
19 regulation does address that as well.

20 MR. WHITLOCK: My name is Rodney Whitlock.
21 I am Vice President for Health Policy at ML Strategies
22 in Washington. I am also a 21 year hill staffer

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1 retired.

2 Start with this which is the Food and Drug
3 and Cosmetic Act speaks to safety and efficacy. It
4 does not speak directly to cost nor does it require
5 FDA to do so. That doesn't mean that it isn't a
6 public policy issue. But when we talk about what the
7 requirements of FDA are that is something to keep in
8 mind is the importance of the value of safety here.

9 Now what is crystal clear about listening to
10 this room is no one here does a bad job. And not
11 surprisingly no one here came to say I'm terrible at
12 what I do and I want to make sure that I have the
13 opportunity to continue to be terrible. Clearly,
14 clearly everyone in this room does an extremely good
15 job and they care about doing so. But that to a
16 degree should guide FDA as they approach this which is
17 if you are trying to set standards which is an FDA
18 requirement to be able to show consistently that they
19 are doing what is in the interest of patient safety it
20 is important that those that are not are weeded out.
21 And currently everyone in this room who does the jobs
22 they do to the level that they do it of damn near

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1 perfection as described no one here should be in any
2 way, shape or form afraid of any standard that FDA
3 could set because you absolutely will meet it;
4 wouldn't you? You've certainly testified to that
5 today. So the question is what is ultimately in the
6 interest of patient safety as FDA moves forward.

7 And I think the argument should be fairly
8 clear that the standards that are certainly in place
9 for the OEMs have a certain expectation for patient
10 safety, without question. And so for ISOs for both in
11 what they do to repair to the previous level, they
12 should have no fear of meeting those levels.

13 And secondly they should have no fear of
14 putting their name on it, on their work. And for the
15 FDA the challenge is what is in the interest of
16 patient safety for this accountability gap to exist
17 moving forward between OEMs and ISOs where there are
18 just functionally different regimes for both when
19 these are issues of patient safety.

20 And finally to say that there is an existing
21 regime out there and particularly to say that
22 ultimately liability is a safety regime, liability

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1 while waiting for a seminal event to occur is no
2 public policy. And FDA certainly knows that for the
3 existence of this entire campus. If they treated
4 drugs that way that would be utterly ridiculous and we
5 all know that. Seminal events as a matter of public
6 policy waiting for those to occur is no public policy.

7 Thank you.

8 MS. SCOTT: Are there any other comments
9 from our audience?

10 If not, I'm going to turn it over again to
11 Sean Boyd who is going to close us out for this
12 afternoon.

13 WRAP-UP

14 CAPT. BOYD: All right. Well thank you all
15 very much for participating in the workshop today.

16 We heard a lot of things that we expected in
17 terms of passion on all sides of this issue to
18 identify the risks and benefits and some of the
19 challenges that we are facing in identifying a path
20 forward.

21 Let me go through some logistics items for
22 tomorrow and then I'll do a little bit of recap in

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1 terms of what we heard and try to clarify some things.

2 So in terms of housekeeping items hold on to
3 your name badges and bring them with you tomorrow.

4 You'll need them to check into the workshop. We are
5 going to start promptly at 8:15 tomorrow morning. And
6 again the food vendors will be available early in the
7 morning if you haven't already had an opportunity to
8 preorder your lunch for tomorrow.

9 In addition to that people that are
10 traveling and if you have luggage, we've reserved room
11 1406 which is one of the break-out rooms that -- help
12 me Valerie, where -- oh, we've changed it to 1504 and
13 it is that direction; is that correct, so if you turn
14 out and go left toward the end of the hall.

15 And I think that is it for logistics and
16 housekeeping items. Am I forgetting anything?

17 Okay. And there will also be some
18 additional table in the back of the large area for any
19 overflow of luggage.

20 So in terms of what we heard today. We
21 started out with a history of some of FDAs efforts and
22 starts and stops in addressing this issue and

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1 certainly we're reconvening today so that we don't
2 find ourselves here again in another 20 years to be
3 tackling this issue once more.

4 We heard some proposed working definitions
5 that are really trying to define the scope of
6 activities that we're talking through today and for
7 future benefit of really the ecosystem that is
8 involved with these issues.

9 We've heard the perspective of a variety of
10 different stakeholder groups and we heard a panel
11 discussion on benefit and risk associated with each of
12 these activities.

13 And I think we heard a lot of common themes
14 and I just wanted to touch on some of those. I
15 certainly might not hit all of them or I might not
16 articulate them in the same way that you would but
17 permit me to share a little bit of what we learned
18 today.

19 First everybody is putting the patient
20 first. We are all focused on patient safety and that
21 is our top priority and our singular priority as we
22 move forward. And that is something that I think is

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1 going to help us continue to come together and focus
2 on lasting solutions as we continue to talk about this
3 tomorrow and after the workshop.

4 Second I think we need to better understand
5 kind of the scope of the problem. We heard varying
6 perspectives on data and anecdotes and what do we
7 really know about what types of risks or issues are
8 going on with servicing activities whether they are
9 performed by and OEM or a third party.

10 We heard a lot of discussion of the
11 importance of visibility and transparency of
12 information really for purposes of documenting the
13 activities that are ongoing for a device's useful life
14 and that is something that I think needs more
15 discussion and exploration.

16 We heard the importance and the value of
17 quality management across all stakeholders that are
18 involved in the issue.

19 There has also been a lot of discussion
20 regarding and a focus on regulation. And one of the
21 things I want to share from an FDA perspective is that
22 we don't have any preconceived solutions to this

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1 problem. We are not necessarily convening this event
2 to publish a regulation that is going to define a
3 future state. We don't know what solutions we're
4 going to bring to the table in partnership with you.
5 And that is something that I really do want to
6 emphasize. We clearly heard that we need to discuss
7 more what is the appropriate level of oversight given
8 the current state of affairs and the varying
9 responsibilities that FDA and other entities might
10 have in ensuring that these activities are performed
11 for the purposes of maintaining patient safety again
12 over a device's useful life?

13 There are a variety of options that we might
14 consider in this.

15 And lastly I want to emphasize that one
16 thing is clear FDA alone is not going to solve or
17 resolve this problem. We together are going to solve
18 and resolve the issues going forward. And I think a
19 lot of these things I was taking notes for kind of
20 closing remarks tomorrow but based on some of the
21 discussion today I wanted to share it early. I think
22 this is a starting point. This workshop is a starting

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1 point, maybe 20 years later a starting point to look
2 at what are we going to do next. And we view our role
3 as convening the key stakeholders around these issues
4 for purposes of defining what solutions we should
5 being to address the concerns that have been raised
6 over this two-day workshop.

7 So with that again I thank you for your
8 participation and I thank you for the passion and the
9 energy that you bring to this. And I look forward to
10 hearing everybody's contributions tomorrow.

11 Have a good night.

12 [Applause]

13 (WHEREUPON, the public meeting concluded for
14 the day.)

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1 CERTIFICATE OF NOTARY PUBLIC

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3 I, NATE RIVENESS, the officer before whom
4 the foregoing deposition was taken, do hereby certify
5 that the witness whose testimony appears in the
6 foregoing deposition was duly sworn by me; that the
7 testimony of said witness was recorded by me and
8 thereafter reduced to typewriting under my direction;
9 that said deposition is a true record of the testimony
10 given by said witness; that I am neither counsel for,
11 related to, nor employed by any of the parties to the
12 action in which this deposition was taken; and,
13 further, that I am not a relative or employee of any
14 counsel or attorney employed by the parties hereto,
15 nor financially or otherwise interested in the outcome
16 of this action.

17

18 NATE RIVENESS

19 Notary Public in and for the

20 State of Maryland

21

22

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1 CERTIFICATE OF TRANSCRIPTION

2

3 I, CHERYL LaSELLE, hereby certify that I am
4 not the Court Reporter who reported the following
5 proceeding and that I have typed the transcript of
6 this proceeding using the Court Reporter's notes and
7 recordings. The foregoing/attached transcript is a
8 true, correct, and complete transcription of said
9 proceeding.

10

11

12

13 _____
Date

14

CHERYL LaSELLE
Transcriptionist

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